

US3402029 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:22:31

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US3402029

Form: Participant Creation

Generated On: 26 Nov 2020 09:22:31

[Participant ID](#)

US3402029

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

US3402029

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

Date of Birth (MMM yyyy)	(b) (6) 1986
Age	34
Age Units	YEARS
Age (Derived)	34
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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:22:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:22:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN JUL 2004
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)	JUL 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

Condition	ANXIETY
Start date (dd MMM yyyy)	UN FEB 2016
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)	FEB 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

Condition	SEVERE OBESITY
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

Condition	CHRONIC HEADACHES
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	27 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	16:08 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 16:08
Height (<i>xxx.x</i>)	165.1 cm
Weight (<i>xxx.x</i>)	336.6 lb
BMI (<i>xxx.x</i>)	56.13029 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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JUL 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*) 27 JUL 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	27 JUL 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	16:06
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	True
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

What was the date of randomization? (dd MMM yyyy) 27 JUL 2020

What was the participant's randomization number? 142074

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

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)	27 JUL 2020
Time of assessment (00:00-23:59)	16:08 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 16:08
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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)	27 JUL 2020
Time of assessment (00:00-23:59)	17:40 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 17:40
Temperature (xxx.x)	36.8 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)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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)	27 JUL 2020
What was the treatment time? (00:00-23:59)	17:07 (24 HR)
Treatment Date and Time (derived)	27 JUL 2020 17:07
Which arm was used to give treatment?	Left Arm ☐
	Right Arm ☒
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	27 JUL 2020
Collection time (<i>00:00-23:59</i>)	16:34 (24 HR)
Collection date and time (derived)	27 JUL 2020 16:34

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

Collection date (<i>dd MMM yyyy</i>)			27 JUL 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:29	27 JUL 2020 16:29
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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**

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 27 JUL 2020 17:27

PC Close Date & Time 27 JUL 2020 19:57

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp 27 JUL 2020 21:43

PC Open Date & Time 27 JUL 2020 18:52

PC Close Date & Time 28 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 28 JUL 2020 18:15

PC Open Date & Time 28 JUL 2020 12:00

PC Close Date & Time 29 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 JUL 2020 18:17

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 15:54

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 16:39

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 11:15

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

96.6 °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

03 AUG 2020 06:44

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 JUL 2020 17:27

PC Close Date & Time

27 JUL 2020 19:57

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

27 JUL 2020 21:44

PC Open Date & Time

27 JUL 2020 18:52

PC Close Date & Time

28 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

28 JUL 2020 18:16

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

29 JUL 2020 18:17

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

30 JUL 2020 15:54

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

31 JUL 2020 16:39

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

02 AUG 2020 11:15

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

03 AUG 2020 06:44

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

27 JUL 2020 17:27

PC Close Date & Time

27 JUL 2020 19:57

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

No ☒

Yes ☐

PC Time stamp	27 JUL 2020 21:45
PC Open Date & Time	27 JUL 2020 18:52
PC Close Date & Time	28 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	28 JUL 2020 18:16
PC Open Date & Time	28 JUL 2020 12:00
PC Close Date & Time	29 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	29 JUL 2020 18:17
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	30 JUL 2020 15:55
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	31 JUL 2020 16:41
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	02 AUG 2020 11:15
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	03 AUG 2020 06:44
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3402029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

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

03 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402029

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402029

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402029

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:00
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	17:02 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 17:02
Temperature (xxx.x)	36.6 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	94 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)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3402029

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3402029

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	24 AUG 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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)	24 AUG 2020
What was the treatment time? (00:00-23:59)	16:30 (24 HR)
Treatment Date and Time (derived)	24 AUG 2020 16:30
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

US3402029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

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

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

Collection date (<i>dd MMM yyyy</i>)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:11	24 AUG 2020 16:11
Nasopharyngeal Swab 2	No		

US3402029

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 17:02

PC Open Date & Time

24 AUG 2020 16:50

PC Close Date & Time

24 AUG 2020 19:20

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 98.8 °F

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

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

PC Time Stamp	25 AUG 2020 06:03
PC Open Date & Time	24 AUG 2020 20:15
PC Close Date & Time	25 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 18:35

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 17:32

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

99.1 °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

27 AUG 2020 23:12

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:45

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

29 AUG 2020 23:42

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

98.6 °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

30 AUG 2020 21:19

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

24 AUG 2020 17:03

PC Open Date & Time

24 AUG 2020 16:50

PC Close Date & Time

24 AUG 2020 19:20

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

25 AUG 2020 06:04

PC Open Date & Time

24 AUG 2020 20:15

PC Close Date & Time

25 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

25 AUG 2020 18:35

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

26 AUG 2020 17:32

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

27 AUG 2020 23:12

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

28 AUG 2020 20:46

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

29 AUG 2020 23:42

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

30 AUG 2020 21:19

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 17:03
PC Open Date & Time	24 AUG 2020 16:50
PC Close Date & Time	24 AUG 2020 19:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 06:04
PC Open Date & Time	24 AUG 2020 20:15
PC Close Date & Time	25 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	25 AUG 2020 20:28
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	26 AUG 2020 17:32
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	27 AUG 2020 23:13
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	28 AUG 2020 20:46
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	29 AUG 2020 23:42
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 ☒

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

Yes ☐	
PC Time stamp	30 AUG 2020 21:20
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3402029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402029

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

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

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402029

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402029

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	18 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:06 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:06
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402029

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

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.

US3402029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

18 SEP 2020 10:15

US3402029

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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	26 SEP 2020 00:02:44
Patient Cloud Open Date & Time	26 SEP 2020 00:01
Patient Cloud Close Date & Time	30 SEP 2020 23:59

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

05 OCT 2020 17:47:46

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

10 OCT 2020 00:01:29

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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	26 OCT 2020 13:29:11
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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	31 OCT 2020 23:55:16
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

Date and time of submission

08 NOV 2020 09:00:23

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 21:07:33

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 SEP 2020 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2020 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 NOV 2020 00:01

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08 NOV 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

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](#)

11 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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17 JAN 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

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07 FEB 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

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17 FEB 2021 00:01

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21 FEB 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	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 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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°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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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13 FEB 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 FEB 2022 00:01

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20 FEB 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 FEB 2022 00:01

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27 FEB 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

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02 MAR 2022 00:01

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06 MAR 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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

Date and time of submission

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09 MAR 2022 00:01

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13 MAR 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

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20 MAR 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

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27 MAR 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 APR 2022 00:01

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10 APR 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

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22 MAY 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

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05 JUN 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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12 JUN 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

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19 JUN 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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26 JUN 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

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03 JUL 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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10 JUL 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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

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 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3402029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT IN CONVALESCENT
PHASE

If Contact Not Made, please provide Comments

US3402029

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402029

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402029

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

US3402029

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:22:31

Date of Contact	30 SEP 2020
Time of Contact	12:45
Date and Time of Contact (derived)	30 SEP 2020 12:45
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 ☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.1 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)	345 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	01 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	100.5 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	349 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	02 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	101.0 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	353 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

	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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	102.0 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	357 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

	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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	04 OCT 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
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)	361 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
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)	365 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

	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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	369 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

	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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	88 %	
O2 Saturation Units	%	
Temperature	101.0 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	373 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	08 OCT 2020	
Assessment Not Done	False	
O2 Saturation	83 %	
O2 Saturation Units	%	
Temperature	101.4 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)	377 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 OCT 2020	
Assessment Not Done	False	
O2 Saturation	88 %	
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)	381 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 OCT 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	97.8 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)	385 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

	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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 OCT 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.9 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)	389 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

	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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	12 OCT 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.2 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)	393 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

	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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	13 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.0 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)	397 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

	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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 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)	401 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 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)	405 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.2 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)	409 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 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)	413 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 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)	417 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	421 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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)	425 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	429 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.0 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)	433 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 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)	437 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.2 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)	441 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 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)	445 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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)	449 of 2761	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

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	☐

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	36.8 C	
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)	453 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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)	457 of 2761	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

	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	☐

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:22:31

Date of Visit	30 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	30 SEP 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

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 05 OCT 2020

End Date 13 OCT 2020

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:

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐
No ☐

Start Date _____

End Date _____

ECMO? Yes ☐
No ☐

Start Date _____

End Date _____

Evidence of Shock:

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

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date _____

Hepatic Dysfunction? Yes ☐
No ☐

Start Date _____

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

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

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:22:31

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3402029

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:22:31

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	02 OCT 2020
Day 5	Yes	04 OCT 2020
Day 7	Yes	06 OCT 2020
Day 9	Yes	08 OCT 2020
Day 14	Yes	13 OCT 2020
Day 21	Yes	20 OCT 2020
Day 28	Yes	27 OCT 2020

US3402029

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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	SICKD1

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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>)	12:05 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 12:05
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	102 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3402029

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:22:31

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 SEP 2020

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	27 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	07:45 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 07:45
Height (<i>xxx.x</i>)	165.5 cm
Weight (<i>xxx.x</i>)	153.1 kg
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3402029

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:22:31

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 OCT 2020

US3402029

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:22:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

AEID	USA-US059-2020-MRNA-1273-P30 1000005
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)	29 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	12 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	13 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	475 of 2761

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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	

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

SUBJECT WAS EXPOSED AT
PLACE OF EMPLOYMENT.
SUBJECT BECAME
SYMPTOMATIC.

SUBJECT WAS DOING BETTER
AS OF 06OCT2020 WHEN
SPOKEN TO FOR NIGHTLY
CONVALESCENT CALL. SITE
WAS NOTIFIED BY A FRIEND
THAT THE SUBJECTS O2
SATURATION WAS DECLINING
AND THAT THE SUBJECT WAS
HAVING DIFFICULTY
BREATHING. SHE THEN WENT
TO THE EMERGENCY ROOM
WHERE SHE WAS LATER
ADMITTED TO THE COVID UNIT
OF THE HOSPITAL. SUBJECT
HAS BEEN STARTED ON
OXYGEN, RAMDESAVIRE AND
CONVALESCENT PLASMA.
SUBJECT ALSO HAD CHEST
XRAY UPON ADMISSION
WHICH SHOWED BIBASILAR
INFILTRATE.

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

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:22:31

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

Yes ☒

No ☐

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

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	137
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 ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

	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 JUL 2004	
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	☒

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	LEXAPRO
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
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 ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

	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 FEB 2016
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	☒

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	MUCINEX
Prophylaxis	Yes ☐ No ☒
Indication	COVID
Dose per administration	600
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 ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

	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)		3 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		06 OCT 2020
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	☒

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes ☐ No ☒
Indication	COVID
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 ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

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

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	DOXYCYCLINE
Prophylaxis	Yes ☐ No ☒
Indication	COVID
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 ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

	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)		07 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	REMDESIVIR
Prophylaxis	Yes ☐ No ☒
Indication	COVID
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

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)	07 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 07 OCT 2020	
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 ☒

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	CONVALESCENT PLASMA
Prophylaxis	Yes ☐ No ☒
Indication	COVID
Dose per administration	1
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 ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

	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)		07 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		08 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	OXYGEN
Prophylaxis	Yes ☐ No ☒
Indication	COVID-19
Dose per administration	4
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 ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

	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)		07 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		11 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	COVID
Dose per administration	1300
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 ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

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

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	EXCEDRIN
Prophylaxis	Yes ☐ No ☒
Indication	COVID
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	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

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

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

Name of Medication	REMDESIVIR
Prophylaxis	Yes ☐ No ☒
Indication	SARS COVID 19
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 ☐

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

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)	08 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy)	12 OCT 2020
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 ☒

US3402029

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:22:31

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402029

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:22:31

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
07 OCT 2020	CHEST X-RAY	Adverse Event	

US3402029

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:22:31

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

US3402029

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:22:31

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 ☐

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US059-2020-MRNA-1273-P301000005
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)	5

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US059-2020-MRNA-1273-P301000005
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)	5
Date of submission (Pre-filled from custom function)	04/OCT/2020 14:34
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.	True

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US059-2020-MRNA-1273-P301000005
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)	5
Date of submission (Pre-filled from custom function)	08/OCT/2020 12:45
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

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US059-2020-MRNA-1273-P301000005
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)	5
Date of submission (Pre-filled from custom function)	12/OCT/2020 14:38
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

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US059-2020-MRNA-1273-P301000005
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)	5
Date of submission (Pre-filled from custom function)	20/OCT/2020 17:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:22:31

SAEID	USA-US059-2020-MRNA-1273-P301000005
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)	5
Date of submission (Pre-filled from custom function)	29/OCT/2020 12:33
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

US3402029 (Prod: Meridian Clinical Research, LLC)

US3402029

Form: Participant Creation

Generated On: 26 Nov 2020 09:22:31

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402029'	RWS_ENDPOINT ENDPOINT (b) (4) 	27 Jul 2020 20:29:24

US3402029

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:40

US3402029

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Jul 2020 20:29:25

US3402029

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:40

US3402029

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	27 Jul 2020 21:21:40

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1986'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Jul 2020 20:29:26

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Age](#)

Audit	User	Time (GMT)
User entered '34'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '34'	System	27 Jul 2020 21:22:14

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[White](#)

Audit	User	Time (GMT)
User entered '1'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

Unknown

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:22:31

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:21:56

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:22:14

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	27 Jul 2020 21:22:14

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '2020'	System	27 Jul 2020 21:22:14

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:22:14

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:22:14

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:22:14

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:22:14

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:22:14

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Jul 2020 20:29:25

US3402029

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:22:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jul 2020 21:22:23

US3402029

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:22:23

US3402029

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:22:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:40:35

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:43:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	28 Jul 2020 14:43:19
Data point term sent to Coder	System	28 Jul 2020 14:42:10
User entered 'hypothyroidism'	Traci Hull (b) (4)	28 Jul 2020 14:41:30
	(b) (4)	

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 17:39:34
User entered 'UN Jul 2004' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:39:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 14:41:30
User entered 'uu Jul 2004' (non-conformant).	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:30

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:30

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:30

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:30

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:30

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Jul 2004'	System	28 Jul 2020 17:39:34
User entered empty.	System	28 Jul 2020 14:41:30

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '2004'	System	28 Jul 2020 17:39:34
User entered empty.	System	28 Jul 2020 14:41:30

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 14:41:30

US3402029

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 14:41:30

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:43:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:43:18
Data point term sent to Coder	System	28 Jul 2020 14:42:11
User entered 'anxiety'	Traci Hull (b) (4)	28 Jul 2020 14:41:52
	(b) (4)	

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'un Feb 2016'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:52

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:52

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:52

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:52

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:41:52

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Feb 2016'	System	28 Jul 2020 14:41:52

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '2016'	System	28 Jul 2020 14:41:52

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 14:41:52

US3402029

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 14:41:52

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:28:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:28:38
Data point term sent to Coder	System	04 Nov 2020 22:27:54
Coding entries removed.	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:46
User entered 'SEVERE OBESITY' reason for change: Per Query Resolution	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 17:42:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 17:42:14
Data point term sent to Coder	System	28 Jul 2020 17:40:47
User entered 'OBESITY'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2004'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '2004'	System	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 17:40:31

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Chronic headaches - version MedDRA\23.0.	Coder Import (b) (4)	30 Jul 2020 18:17:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Jul 2020 18:17:09
Data point term sent to Coder	System	30 Jul 2020 18:16:09
User entered 'chronic headaches'	Traci Hull (b) (4)	30 Jul 2020 18:15:20
	(b) (4)	

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Traci Hull (b) (4) (b) (4)	30 Jul 2020 18:15:20

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	30 Jul 2020 18:15:20

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Jul 2020 18:15:20

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	30 Jul 2020 18:15:20

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	30 Jul 2020 18:15:20

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	30 Jul 2020 18:15:20

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '2010'	System	30 Jul 2020 18:15:20

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	30 Jul 2020 18:15:20

US3402029

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	30 Jul 2020 18:15:20

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '16:08'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Jul 2020 16:08'	System	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '165.1' cm	Traci Hull (b) (4)	28 Jul 2020 14:43:19
DataPoint set to visible.	(b) (4) System	27 Jul 2020 21:22:23

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '336.6' lb	Traci Hull (b) (4)	28 Jul 2020 14:43:19
DataPoint set to visible.	(b) (4) System	27 Jul 2020 21:22:23

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '56.13029'	System	16 Sep 2020 23:36:59
User entered '56.1'	System	28 Jul 2020 14:43:19
DataPoint set to visible.	System	27 Jul 2020 21:22:23

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	28 Jul 2020 14:43:19
DataPoint set to visible.	System	27 Jul 2020 21:22:23

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
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)	07 Nov 2020 18:44:47
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 'DATA UPDATED ND' (Site from DM).	Tammy Kohn (b) (4)	06 Nov 2020 15:34:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	06 Nov 2020 15:34:04
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).	(b) (4), (b) (6)	06 Nov 2020 15:04:52
User entered '36.6' C	Traci Hull (b) (4)	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	06 Nov 2020 15:34:04
User entered 'Oral (Oral)'	Traci Hull (b) (4)	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	06 Nov 2020 15:34:04
User entered '100'	Traci Hull (b) (4)	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	06 Nov 2020 15:34:04
User entered '18'	(b) (4)	
	Traci Hull (b) (4)	28 Jul 2020 14:43:19
	(b) (4)	

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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)	06 Nov 2020 15:34:04
User entered '132'	Traci Hull (b) (4)	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[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)	06 Nov 2020 15:34:04
User entered '84'	Traci Hull (b) (4)	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 14:43:19

US3402029

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:44:23

US3402029

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[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)	27 Aug 2020 13:10:01
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		24 Aug 2020 21:39:53
User entered '27 Jul 2020'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:44:23

US3402029

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:45:13

US3402029

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:45:13

US3402029

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:45:13

US3402029

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:45:13

US3402029

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:45:13

US3402029

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:45:13

US3402029

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:45:13

US3402029

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:22:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:45:13

US3402029

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:52:36

US3402029

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:52:36

US3402029

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:52:36

US3402029

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:52:36

US3402029

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:52:36

US3402029

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:52:36

US3402029

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Collection time](#)

Audit	User	Time (GMT)
User entered '16:06'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:52:36

US3402029

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 14:52:36

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:46:02

US3402029

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:22:31

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:46:02

US3402029

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:46:22
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	28 Jul 2020 17:24:05
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:46:22
User entered '27 Jul 2020'	Tarin Gordon (b) (4)	28 Jul 2020 17:24:05
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:46:22
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4)	28 Jul 2020 17:24:05
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Jul 2020 17:24:05

US3402029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:10
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:29:29

US3402029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:10
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:04:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:04:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jul 2020 20:29:29
User entered '142074' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:29:29

US3402029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:10
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 20:29:29

US3402029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:10
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:26:37

US3402029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:10
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:26:37

US3402029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:10
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	28 Jul 2020 17:26:37
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:10
User entered 'No (N)'	Tarin Gordon (b) (4)	28 Jul 2020 17:26:37
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:22:31

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:10
User entered 'No (N)'	Tarin Gordon (b) (4)	28 Jul 2020 17:26:37
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:45:07
Query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' answered with 'DATA UPDATED TO ND' (Site from DM).	Tammy Kohn (b) (4)	06 Nov 2020 15:34:39
DataPoint Un-verified.	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	06 Nov 2020 15:34:31
User opened query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:53:26
User entered '165.1' cm	(b) (4), (b) (6)	09 Oct 2020 19:47:20
	(b) (4)	
	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

[Weight](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Tammy Kohn (b) (4)	06 Nov 2020 15:34:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	06 Nov 2020 15:34:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '152.7' kg	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:45:07
Query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' answered with 'DATA UPDATED TO ND' (Site from DM).	Tammy Kohn (b) (4)	06 Nov 2020 15:34:39
DataPoint Un-verified.	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	06 Nov 2020 15:34:31
User opened query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:53:26
User entered '165.1' cm	(b) (4), (b) (6)	09 Oct 2020 19:47:20
	(b) (4)	
	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

[Weight](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Tammy Kohn (b) (4)	06 Nov 2020 15:34:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	06 Nov 2020 15:34:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '152.7' kg	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '27 Jul 2020'	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	28 Jul 2020 17:34:20
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	28 Jul 2020 17:32:44
User entered '16:08'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Jul 2020 16:08'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '36.6' C	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered empty.	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '100'	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '18'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '132'	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '84'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:45:07
Query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' answered with 'DATA UPDATED TO ND' (Site from DM).	Tammy Kohn (b) (4)	06 Nov 2020 15:34:39
DataPoint Un-verified.	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	06 Nov 2020 15:34:31
User opened query 'Per CDM: Per CCGs, as Height and Weight are recorded at Screening visit already, please enter ND in the data field of the eCRF for Height and Weight at this visit and uncheck the units.' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:53:26
User entered '165.1' cm	(b) (4), (b) (6)	09 Oct 2020 19:47:20
	(b) (4)	
	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:22:31

[Weight](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Tammy Kohn (b) (4)	06 Nov 2020 15:34:31
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Tammy Kohn (b) (4)	06 Nov 2020 15:34:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '152.7' kg	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '27 Jul 2020'	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
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)	14 Aug 2020 18:45:46
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)	28 Jul 2020 22:48:30
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)	28 Jul 2020 17:34:20
User entered '17:40'	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Jul 2020 17:40'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '36.8' C	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered empty.	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '96'	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '18'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '132'	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:20
User entered '86'	Tarin Gordon (b) (4)	28 Jul 2020 17:32:44
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 17:32:44

US3402029

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:32
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	28 Jul 2020 17:36:50
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:32
User entered '27 Jul 2020'	Tarin Gordon (b) (4)	28 Jul 2020 17:36:50
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:46
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	17 Sep 2020 19:46:39
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	28 Jul 2020 17:37:34

US3402029

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:46
User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:05:42
Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'Data updated' (Site from DM).	Tammy Kohn (b) (4)	17 Sep 2020 19:46:50
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	17 Sep 2020 19:46:39
User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 15:01:54
User entered '27 Jul 2020'	Tarin Gordon (b) (4)	28 Jul 2020 17:37:34

US3402029

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Test performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:46
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	17 Sep 2020 19:46:39
User entered 'Urine (URINE)'	Tarin Gordon (b) (4)	28 Jul 2020 17:37:34

US3402029

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Result](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:46
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	17 Sep 2020 19:46:39
User entered 'Negative (NEGATIVE)'	Tarin Gordon (b) (4)	28 Jul 2020 17:37:34

US3402029

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:46
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	17 Sep 2020 19:46:39
User entered 'No (N)'	Tarin Gordon (b) (4)	28 Jul 2020 17:37:34

US3402029

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Collection date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:46
User entered empty.	Tarin Gordon (b) (4)	28 Jul 2020 17:37:34
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Collection time](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:47:46
User entered empty.	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:37:34

US3402029

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 17:37:34

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:27
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	27 Jul 2020 21:22:51
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:27
User entered empty.	Tarin Gordon (b) (4)	27 Jul 2020 21:22:51
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:27
User entered empty.	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:22:51

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	27 Jul 2020 21:22:51

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:27
User entered '27 Jul 2020'	Tarin Gordon (b) (4)	27 Jul 2020 21:22:51
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:27
User entered '17:07' reason for change: Data Entry Error	Tarin Gordon (b) (4)	28 Jul 2020 17:34:20
User entered '15:07'	Tarin Gordon (b) (4)	27 Jul 2020 21:22:51

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Jul 2020 17:07'	System	28 Jul 2020 17:34:20
User entered '27 Jul 2020 15:07'	System	27 Jul 2020 21:22:51

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:27
User entered 'Right Arm (RIGHT ARM)'	Tarin Gordon (b) (4) (b) (4)	27 Jul 2020 21:22:51

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:27
User entered 'ONCE'	System	27 Jul 2020 21:22:51

US3402029

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	27 Jul 2020 21:22:51

US3402029

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:55
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:37:56

US3402029

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:55
User entered '27 Jul 2020'	Tarin Gordon (b) (4)	28 Jul 2020 17:37:56
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:48:55
User entered '16:34'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:37:56

US3402029

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Jul 2020 16:34'	System	28 Jul 2020 17:37:56

US3402029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:49:07
User entered '27 Jul 2020'	Tarin Gordon (b) (4)	28 Jul 2020 17:38:18
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:38:18

US3402029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:49:07
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:38:18

US3402029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:49:07
User entered '16:29'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:38:18

US3402029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Jul 2020 16:29'	System	28 Jul 2020 17:38:18

US3402029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:38:18

US3402029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:49:07
User entered 'No (N)'	Tarin Gordon (b) (4)	28 Jul 2020 17:38:18
	(b) (4)	

US3402029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:49:07
User entered empty.	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:38:18

US3402029

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 17:38:18

US3402029

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:49:15
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	28 Jul 2020 17:38:27

US3402029

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 17:38:27

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 17:27'	System	28 Jul 2020 17:34:20
User entered '27 Jul 2020 15:27'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 19:57'	System	28 Jul 2020 17:34:20
User entered '27 Jul 2020 17:57'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 1, after vaccination (at home)'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:43:37', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '26cd0dac-f2b2-4bfa-8777-c57190fd6765'	System	28 Jul 2020 01:43:58
User entered 'Yes (Y)'	System	28 Jul 2020 01:43:58

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:43:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '26cd0dac-f2b2-4bfa-8777-c57190fd6765'	System	28 Jul 2020 01:43:58
User entered '97.3'	System	28 Jul 2020 01:43:58

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:43:48', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '26cd0dac-f2b2-4bfa-8777-c57190fd6765'	System	28 Jul 2020 01:43:58
User entered 'No (N)'	System	28 Jul 2020 01:43:58

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:43:54', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '26cd0dac-f2b2-4bfa-8777-c57190fd6765'	System	28 Jul 2020 01:43:58
User entered '27 Jul 2020 21:43'	System	28 Jul 2020 01:43:58

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 18:52'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 2'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:14:49', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '1fb3a368-f81e-471f-87bd-d70173e1cdb7'	System	28 Jul 2020 22:15:12
User entered 'Yes (Y)'	System	28 Jul 2020 22:15:12

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:14:55', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '1fb3a368-f81e-471f-87bd-d70173e1cdb7'	System	28 Jul 2020 22:15:12
User entered '98.2'	System	28 Jul 2020 22:15:12

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:14:59', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '1fb3a368-f81e-471f-87bd-d70173e1cdb7'	System	28 Jul 2020 22:15:12
User entered 'Yes (Y)'	System	28 Jul 2020 22:15:12

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'MILD HEADACHE, MILD FATIGUE' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 09:09:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:15:04', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '1fb3a368-f81e-471f-87bd-d70173e1cdb7'	Tammy Kohn (b) (4)	11 Sep 2020 17:09:30
User entered '1'	System	28 Jul 2020 22:15:12
	System	28 Jul 2020 22:15:12
	System	28 Jul 2020 22:15:12

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:15:04', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '1fb3a368-f81e-471f-87bd-d70173e1cdb7'	System	28 Jul 2020 22:15:12
User entered '0'	System	28 Jul 2020 22:15:12

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:15:09', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '1fb3a368-f81e-471f-87bd-d70173e1cdb7'	System	28 Jul 2020 22:15:12
User entered '28 Jul 2020 18:15'	System	28 Jul 2020 22:15:12

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 3'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:12', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '41ae4b1a-609d-4e86-925e-716b7583c2c2'	System	29 Jul 2020 22:17:22
User entered 'Yes (Y)'	System	29 Jul 2020 22:17:22

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:15', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '41ae4b1a-609d-4e86-925e-716b7583c2c2'	System	29 Jul 2020 22:17:22
User entered '98.2'	System	29 Jul 2020 22:17:22

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:17', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '41ae4b1a-609d-4e86-925e-716b7583c2c2'	System	29 Jul 2020 22:17:22
User entered 'No (N)'	System	29 Jul 2020 22:17:22

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:20', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '41ae4b1a-609d-4e86-925e-716b7583c2c2'	System	29 Jul 2020 22:17:22
User entered '29 Jul 2020 18:17'	System	29 Jul 2020 22:17:22

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 4'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:28', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '05d190a0-45fc-4e17-87b2-1b58e17993b3'	System	30 Jul 2020 19:54:42
User entered 'Yes (Y)'	System	30 Jul 2020 19:54:42

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:36', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '05d190a0-45fc-4e17-87b2-1b58e17993b3'	System	30 Jul 2020 19:54:42
User entered '98.2'	System	30 Jul 2020 19:54:42

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:39', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '05d190a0-45fc-4e17-87b2-1b58e17993b3'	System	30 Jul 2020 19:54:42
User entered 'No (N)'	System	30 Jul 2020 19:54:42

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:41', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '05d190a0-45fc-4e17-87b2-1b58e17993b3'	System	30 Jul 2020 19:54:42
User entered '30 Jul 2020 15:54'	System	30 Jul 2020 19:54:42

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 5'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:39:19', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'a5030706-e2bc-4d0c-be36-7844a0a5c340'	System	31 Jul 2020 20:39:35
User entered 'Yes (Y)'	System	31 Jul 2020 20:39:35

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:39:26', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'a5030706-e2bc-4d0c-be36-7844a0a5c340' User entered '97.7'	System	31 Jul 2020 20:39:35

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:39:29', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'a5030706-e2bc-4d0c-be36-7844a0a5c340'	System	31 Jul 2020 20:39:35
User entered 'No (N)'	System	31 Jul 2020 20:39:35

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:39:32', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'a5030706-e2bc-4d0c-be36-7844a0a5c340' User entered '31 Jul 2020 16:39'	System	31 Jul 2020 20:39:35
	System	31 Jul 2020 20:39:35

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 6'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:10', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'c84bbcb2-c75c-44f6-99a3-15c5a4f04020'	System	02 Aug 2020 15:15:23
User entered 'Yes (Y)'	System	02 Aug 2020 15:15:23

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:14', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'c84bbcb2-c75c-44f6-99a3-15c5a4f04020'	System	02 Aug 2020 15:15:23
User entered '98.8'	System	02 Aug 2020 15:15:23

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:16', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'c84bbcb2-c75c-44f6-99a3-15c5a4f04020'	System	02 Aug 2020 15:15:23
User entered 'No (N)'	System	02 Aug 2020 15:15:23

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:18', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'c84bbcb2-c75c-44f6-99a3-15c5a4f04020'	System	02 Aug 2020 15:15:23
User entered '02 Aug 2020 11:15'	System	02 Aug 2020 15:15:23

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 7'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:16', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b8f6e05c-4e24-49c6-a3e1-10c9519b9830'	System	03 Aug 2020 10:44:25
User entered 'Yes (Y)'	System	03 Aug 2020 10:44:25

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:20', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b8f6e05c-4e24-49c6-a3e1-10c9519b9830'	System	03 Aug 2020 10:44:25
User entered '96.6'	System	03 Aug 2020 10:44:25

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:22', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b8f6e05c-4e24-49c6-a3e1-10c9519b9830'	System	03 Aug 2020 10:44:25
User entered 'No (N)'	System	03 Aug 2020 10:44:25

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:24', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b8f6e05c-4e24-49c6-a3e1-10c9519b9830'	System	03 Aug 2020 10:44:25
User entered '03 Aug 2020 06:44'	System	03 Aug 2020 10:44:25

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 17:27'	System	28 Jul 2020 17:34:20
User entered '27 Jul 2020 15:27'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 19:57'	System	28 Jul 2020 17:34:20
User entered '27 Jul 2020 17:57'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 1, after vaccination (at home)'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:44:03', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '72ff2e7f-fd85-4a1f-885c-89b034e72924'	System	28 Jul 2020 01:44:36
User entered 'None (1)'	System	28 Jul 2020 01:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:44:05', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '72ff2e7f-fd85-4a1f-885c-89b034e72924'	System	28 Jul 2020 01:44:36
User entered 'No (N)'	System	28 Jul 2020 01:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:44:21', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '72ff2e7f-fd85-4a1f-885c-89b034e72924'	System	28 Jul 2020 01:44:36
User entered 'No (N)'	System	28 Jul 2020 01:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:44:29', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '72ff2e7f-fd85-4a1f-885c-89b034e72924'	System	28 Jul 2020 01:44:36
User entered 'None (1)'	System	28 Jul 2020 01:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:44:35', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '72ff2e7f-fd85-4a1f-885c-89b034e72924'	System	28 Jul 2020 01:44:36
User entered '27 Jul 2020 21:44'	System	28 Jul 2020 01:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 18:52'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 2'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:15:51', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5a22d905-0459-4c74-b9f4-04c1070eacf7'	System	28 Jul 2020 22:16:02
User entered 'None (1)'	System	28 Jul 2020 22:16:02

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:15:53', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5a22d905-0459-4c74-b9f4-04c1070eacf7'	System	28 Jul 2020 22:16:02
User entered 'No (N)'	System	28 Jul 2020 22:16:02

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:15:55', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5a22d905-0459-4c74-b9f4-04c1070eacf7'	System	28 Jul 2020 22:16:02
User entered 'No (N)'	System	28 Jul 2020 22:16:02

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:15:58', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5a22d905-0459-4c74-b9f4-04c1070eacf7'	System	28 Jul 2020 22:16:02
User entered 'None (1)'	System	28 Jul 2020 22:16:02

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:16:00', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5a22d905-0459-4c74-b9f4-04c1070eacf7'	System	28 Jul 2020 22:16:02
User entered '28 Jul 2020 18:16'	System	28 Jul 2020 22:16:02

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 3'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:23', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'a94596ec-c89d-410c-a4be-e419efb28337'	System	29 Jul 2020 22:17:34
User entered 'None (1)'	System	29 Jul 2020 22:17:34

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:26', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'a94596ec-c89d-410c-a4be-e419efb28337'	System	29 Jul 2020 22:17:34
User entered 'No (N)'	System	29 Jul 2020 22:17:34

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:28', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'a94596ec-c89d-410c-a4be-e419efb28337'	System	29 Jul 2020 22:17:34
User entered 'No (N)'	System	29 Jul 2020 22:17:34

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:30', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'a94596ec-c89d-410c-a4be-e419efb28337'	System	29 Jul 2020 22:17:34
User entered 'None (1)'	System	29 Jul 2020 22:17:34

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:32', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'a94596ec-c89d-410c-a4be-e419efb28337'	System	29 Jul 2020 22:17:34
User entered '29 Jul 2020 18:17'	System	29 Jul 2020 22:17:34

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 4'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'f8c49fd4-42b3-4865-9b3d-d0290704c28e'	System	30 Jul 2020 19:54:57
User entered 'None (1)'	System	30 Jul 2020 19:54:57

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:46', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'f8c49fd4-42b3-4865-9b3d-d0290704c28e'	System	30 Jul 2020 19:54:57
User entered 'No (N)'	System	30 Jul 2020 19:54:57

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:48', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'f8c49fd4-42b3-4865-9b3d-d0290704c28e'	System	30 Jul 2020 19:54:57
User entered 'No (N)'	System	30 Jul 2020 19:54:57

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:51', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'f8c49fd4-42b3-4865-9b3d-d0290704c28e'	System	30 Jul 2020 19:54:57
User entered 'None (1)'	System	30 Jul 2020 19:54:57

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:54', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'f8c49fd4-42b3-4865-9b3d-d0290704c28e'	System	30 Jul 2020 19:54:57
User entered '30 Jul 2020 15:54'	System	30 Jul 2020 19:54:57

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 5'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:39:46', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5798a808-9842-4b57-869d-aa83802ca54d'	System	31 Jul 2020 20:39:59
User entered 'None (1)'	System	31 Jul 2020 20:39:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:39:48', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5798a808-9842-4b57-869d-aa83802ca54d'	System	31 Jul 2020 20:39:59
User entered 'No (N)'	System	31 Jul 2020 20:39:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:39:50', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5798a808-9842-4b57-869d-aa83802ca54d'	System	31 Jul 2020 20:39:59
User entered 'No (N)'	System	31 Jul 2020 20:39:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:39:52', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5798a808-9842-4b57-869d-aa83802ca54d'	System	31 Jul 2020 20:39:59
User entered 'None (1)'	System	31 Jul 2020 20:39:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:39:54', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5798a808-9842-4b57-869d-aa83802ca54d'	System	31 Jul 2020 20:39:59
User entered '31 Jul 2020 16:39'	System	31 Jul 2020 20:39:59

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 6'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:22', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'af432eef-81c2-4839-b782-ce286e6096c7'	System	02 Aug 2020 15:15:33
User entered 'None (1)'	System	02 Aug 2020 15:15:33

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:23', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'af432eef-81c2-4839-b782-ce286e6096c7'	System	02 Aug 2020 15:15:33
User entered 'No (N)'	System	02 Aug 2020 15:15:33

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:25', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'af432eef-81c2-4839-b782-ce286e6096c7'	System	02 Aug 2020 15:15:33
User entered 'No (N)'	System	02 Aug 2020 15:15:33

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:26', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'af432eef-81c2-4839-b782-ce286e6096c7'	System	02 Aug 2020 15:15:33
User entered 'None (1)'	System	02 Aug 2020 15:15:33

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:28', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'af432eef-81c2-4839-b782-ce286e6096c7'	System	02 Aug 2020 15:15:33
User entered '02 Aug 2020 11:15'	System	02 Aug 2020 15:15:33

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 7'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:27', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '3e6e648b-8635-4032-becd-fb9201e0e3aa'	System	03 Aug 2020 10:44:36
User entered 'None (1)'	System	03 Aug 2020 10:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:29', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '3e6e648b-8635-4032-becd-fb9201e0e3aa'	System	03 Aug 2020 10:44:36
User entered 'No (N)'	System	03 Aug 2020 10:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:30', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '3e6e648b-8635-4032-becd-fb9201e0e3aa'	System	03 Aug 2020 10:44:36
User entered 'No (N)'	System	03 Aug 2020 10:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:33', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '3e6e648b-8635-4032-becd-fb9201e0e3aa'	System	03 Aug 2020 10:44:36
User entered 'None (1)'	System	03 Aug 2020 10:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:35', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '3e6e648b-8635-4032-becd-fb9201e0e3aa'	System	03 Aug 2020 10:44:36
User entered '03 Aug 2020 06:44'	System	03 Aug 2020 10:44:36

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 17:27'	System	28 Jul 2020 17:34:20
User entered '27 Jul 2020 15:27'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 19:57'	System	28 Jul 2020 17:34:20
User entered '27 Jul 2020 17:57'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 1, after vaccination (at home)'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:44:41', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b4803074-17da-4baa-9fa7-ddd2c64eachb7'	System	28 Jul 2020 01:45:10
User entered 'None (0)'	System	28 Jul 2020 01:45:10

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:44:54', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b4803074-17da-4baa-9fa7-ddd2c64eachb7'	System	28 Jul 2020 01:45:10
User entered 'None (0)'	System	28 Jul 2020 01:45:10

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:44:56', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b4803074-17da-4baa-9fa7-ddd2c64eachb7'	System	28 Jul 2020 01:45:10
User entered 'None (0)'	System	28 Jul 2020 01:45:10

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:44:58', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b4803074-17da-4baa-9fa7-ddd2c64eachb7'	System	28 Jul 2020 01:45:10
User entered 'None (0)'	System	28 Jul 2020 01:45:10

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:45:00', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b4803074-17da-4baa-9fa7-ddd2c64eachb7'	System	28 Jul 2020 01:45:10
User entered 'None (0)'	System	28 Jul 2020 01:45:10

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:45:02', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b4803074-17da-4baa-9fa7-ddd2c64eachb7'	System	28 Jul 2020 01:45:10
User entered 'None (0)'	System	28 Jul 2020 01:45:10

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:45:06', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b4803074-17da-4baa-9fa7-ddd2c64eachb7'	System	28 Jul 2020 01:45:10
User entered 'No (N)'	System	28 Jul 2020 01:45:10

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-27T21:45:08', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b4803074-17da-4baa-9fa7-ddd2c64eachb7'	System	28 Jul 2020 01:45:10
User entered '27 Jul 2020 21:45'	System	28 Jul 2020 01:45:10

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 18:52'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 2'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:16:34', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'cb4a278f-0d67-45f2-9e53-47d62f05566e'	System	28 Jul 2020 22:16:53
User entered 'No interference with activity (1)'	System	28 Jul 2020 22:16:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:16:37', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'cb4a278f-0d67-45f2-9e53-47d62f05566e'	System	28 Jul 2020 22:16:53
User entered 'No interference with activity (1)'	System	28 Jul 2020 22:16:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:16:39', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'cb4a278f-0d67-45f2-9e53-47d62f05566e'	System	28 Jul 2020 22:16:53
User entered 'None (0)'	System	28 Jul 2020 22:16:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:16:42', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'cb4a278f-0d67-45f2-9e53-47d62f05566e'	System	28 Jul 2020 22:16:53
User entered 'None (0)'	System	28 Jul 2020 22:16:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:16:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'cb4a278f-0d67-45f2-9e53-47d62f05566e'	System	28 Jul 2020 22:16:53
User entered 'None (0)'	System	28 Jul 2020 22:16:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:16:46', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'cb4a278f-0d67-45f2-9e53-47d62f05566e'	System	28 Jul 2020 22:16:53
User entered 'None (0)'	System	28 Jul 2020 22:16:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:16:49', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'cb4a278f-0d67-45f2-9e53-47d62f05566e'	System	28 Jul 2020 22:16:53
User entered 'No (N)'	System	28 Jul 2020 22:16:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-28T18:16:51', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'cb4a278f-0d67-45f2-9e53-47d62f05566e'	System	28 Jul 2020 22:16:53
User entered '28 Jul 2020 18:16'	System	28 Jul 2020 22:16:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 3'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:35', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'efd19e1f-debc-4ef8-9a2d-7b857e8ffda6'	System	29 Jul 2020 22:17:51
User entered 'None (0)'	System	29 Jul 2020 22:17:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:37', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'efd19e1f-debc-4ef8-9a2d-7b857e8ffda6'	System	29 Jul 2020 22:17:51
User entered 'None (0)'	System	29 Jul 2020 22:17:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:39', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'efd19e1f-debc-4ef8-9a2d-7b857e8ffda6'	System	29 Jul 2020 22:17:51
User entered 'None (0)'	System	29 Jul 2020 22:17:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:41', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'efd19e1f-debc-4ef8-9a2d-7b857e8ffda6'	System	29 Jul 2020 22:17:51
User entered 'None (0)'	System	29 Jul 2020 22:17:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:43', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'efd19e1f-debc-4ef8-9a2d-7b857e8ffda6'	System	29 Jul 2020 22:17:51
User entered 'None (0)'	System	29 Jul 2020 22:17:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:45', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'efd19e1f-debc-4ef8-9a2d-7b857e8ffda6'	System	29 Jul 2020 22:17:51
User entered 'None (0)'	System	29 Jul 2020 22:17:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:46', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'efd19e1f-debc-4ef8-9a2d-7b857e8ffda6'	System	29 Jul 2020 22:17:51
User entered 'No (N)'	System	29 Jul 2020 22:17:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-29T18:17:48', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'efd19e1f-debc-4ef8-9a2d-7b857e8ffda6'	System	29 Jul 2020 22:17:51
User entered '29 Jul 2020 18:17'	System	29 Jul 2020 22:17:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 4'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:57', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '50e81941-f3a0-4d1c-b124-4038df495a1d'	System	30 Jul 2020 19:55:13
User entered 'None (0)'	System	30 Jul 2020 19:55:13

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:54:59', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '50e81941-f3a0-4d1c-b124-4038df495a1d' User entered 'None (0)'	System	30 Jul 2020 19:55:13
	System	30 Jul 2020 19:55:13

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:55:01', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '50e81941-f3a0-4d1c-b124-4038df495a1d' User entered 'None (0)'	System	30 Jul 2020 19:55:13
	System	30 Jul 2020 19:55:13

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:55:02', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '50e81941-f3a0-4d1c-b124-4038df495a1d' User entered 'None (0)'	System	30 Jul 2020 19:55:13
	System	30 Jul 2020 19:55:13

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:55:05', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '50e81941-f3a0-4d1c-b124-4038df495a1d'	System	30 Jul 2020 19:55:13
User entered 'None (0)'	System	30 Jul 2020 19:55:13

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:55:07', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '50e81941-f3a0-4d1c-b124-4038df495a1d'	System	30 Jul 2020 19:55:13
User entered 'None (0)'	System	30 Jul 2020 19:55:13

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:55:09', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '50e81941-f3a0-4d1c-b124-4038df495a1d' User entered 'No (N)'	System	30 Jul 2020 19:55:13

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-30T15:55:11', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '50e81941-f3a0-4d1c-b124-4038df495a1d' User entered '30 Jul 2020 15:55'	System	30 Jul 2020 19:55:13
	System	30 Jul 2020 19:55:13

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 5'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:40:16', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5397e6d2-2470-474a-931f-b404f3be9133'	System	31 Jul 2020 20:41:55
User entered 'None (0)'	System	31 Jul 2020 20:41:55

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:40:36', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5397e6d2-2470-474a-931f-b404f3be9133'	System	31 Jul 2020 20:41:55
User entered 'None (0)'	System	31 Jul 2020 20:41:55

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:40:38', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5397e6d2-2470-474a-931f-b404f3be9133'	System	31 Jul 2020 20:41:55
User entered 'None (0)'	System	31 Jul 2020 20:41:55

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:41:25', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5397e6d2-2470-474a-931f-b404f3be9133'	System	31 Jul 2020 20:41:55
User entered 'None (0)'	System	31 Jul 2020 20:41:55

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:41:45', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5397e6d2-2470-474a-931f-b404f3be9133'	System	31 Jul 2020 20:41:55
User entered 'None (0)'	System	31 Jul 2020 20:41:55

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:41:48', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5397e6d2-2470-474a-931f-b404f3be9133'	System	31 Jul 2020 20:41:55
User entered 'None (0)'	System	31 Jul 2020 20:41:55

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:41:51', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5397e6d2-2470-474a-931f-b404f3be9133'	System	31 Jul 2020 20:41:55
User entered 'No (N)'	System	31 Jul 2020 20:41:55

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-07-31T16:41:53', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '5397e6d2-2470-474a-931f-b404f3be9133'	System	31 Jul 2020 20:41:55
User entered '31 Jul 2020 16:41'	System	31 Jul 2020 20:41:55

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Jul 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 6'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:32', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ef3e07ea-03ae-464e-bef6-a45140f0123c'	System	02 Aug 2020 15:15:49
User entered 'None (0)'	System	02 Aug 2020 15:15:49

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:35', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ef3e07ea-03ae-464e-bef6-a45140f0123c' User entered 'None (0)'	System	02 Aug 2020 15:15:49
	System	02 Aug 2020 15:15:49

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:37', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ef3e07ea-03ae-464e-bef6-a45140f0123c'	System	02 Aug 2020 15:15:49
User entered 'None (0)'	System	02 Aug 2020 15:15:49

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:38', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ef3e07ea-03ae-464e-bef6-a45140f0123c' User entered 'None (0)'	System	02 Aug 2020 15:15:49
	System	02 Aug 2020 15:15:49

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:39', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ef3e07ea-03ae-464e-bef6-a45140f0123c'	System	02 Aug 2020 15:15:49
User entered 'None (0)'	System	02 Aug 2020 15:15:49

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:41', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ef3e07ea-03ae-464e-bef6-a45140f0123c'	System	02 Aug 2020 15:15:49
User entered 'None (0)'	System	02 Aug 2020 15:15:49

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:42', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ef3e07ea-03ae-464e-bef6-a45140f0123c'	System	02 Aug 2020 15:15:49
User entered 'No (N)'	System	02 Aug 2020 15:15:49

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-02T11:15:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ef3e07ea-03ae-464e-bef6-a45140f0123c'	System	02 Aug 2020 15:15:49
User entered '02 Aug 2020 11:15'	System	02 Aug 2020 15:15:49

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 7'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:38', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4166dab0-9e75-4d68-8df2-ef76188d256f' User entered 'None (0)'	System	03 Aug 2020 10:44:53
	System	03 Aug 2020 10:44:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:39', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4166dab0-9e75-4d68-8df2-ef76188d256f' User entered 'None (0)'	System	03 Aug 2020 10:44:53
	System	03 Aug 2020 10:44:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:42', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4166dab0-9e75-4d68-8df2-ef76188d256f' User entered 'None (0)'	System	03 Aug 2020 10:44:53
	System	03 Aug 2020 10:44:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4166dab0-9e75-4d68-8df2-ef76188d256f' User entered 'None (0)'	System	03 Aug 2020 10:44:53
	System	03 Aug 2020 10:44:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:46', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4166dab0-9e75-4d68-8df2-ef76188d256f' User entered 'None (0)'	System	03 Aug 2020 10:44:53
	System	03 Aug 2020 10:44:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:48', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4166dab0-9e75-4d68-8df2-ef76188d256f' User entered 'None (0)'	System	03 Aug 2020 10:44:53
	System	03 Aug 2020 10:44:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:49', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4166dab0-9e75-4d68-8df2-ef76188d256f'	System	03 Aug 2020 10:44:53
User entered 'No (N)'	System	03 Aug 2020 10:44:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-03T06:44:51', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4166dab0-9e75-4d68-8df2-ef76188d256f' User entered '03 Aug 2020 06:44'	System	03 Aug 2020 10:44:53
	System	03 Aug 2020 10:44:53

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	27 Jul 2020 21:22:51

US3402029

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:50:44
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:55:57

US3402029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:03:18
	(b) (4)	
User entered '03 Aug 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:03:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:50:44
User entered '3 Aug 2020'	Traci Hull (b) (4)	11 Aug 2020 18:55:57
	(b) (4)	

US3402029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:50:44
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:55:57

US3402029

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:50:44
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:55:57

US3402029

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:50:52
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:56:06

US3402029

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:56:06

US3402029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:51:16
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:56:17

US3402029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:51:16
User entered '10 Aug 2020'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:56:17

US3402029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:51:16
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:56:17

US3402029

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:51:16
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:56:17

US3402029

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:51:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Aug 2020 18:56:25

US3402029

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:56:25

US3402029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Aug 2020 11:28:51

US3402029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Traci Hull (b) (4) (b) (4)	18 Aug 2020 11:28:51

US3402029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[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)	18 Aug 2020 11:28:51

US3402029

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Aug 2020 11:28:51

US3402029

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4)	25 Aug 2020 21:05:30
User entered 'No (N)' reason for change: Data Entry Error	Traci Hull (b) (4)	25 Aug 2020 21:05:22
User entered 'Yes (Y)'	Traci Hull (b) (4)	18 Aug 2020 11:28:57

US3402029

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 21:05:30
User entered empty.	System	25 Aug 2020 21:05:22
User entered '1'	System	18 Aug 2020 11:28:57

US3402029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:39:53

US3402029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:39:53

US3402029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[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)	24 Aug 2020 21:39:53

US3402029

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	24 Aug 2020 21:39:53

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '16:00'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:00'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '92'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '18'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '86'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '17:02'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 17:02'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '94'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '18'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '128'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '82'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 21:41:04

US3402029

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:14

US3402029

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:14

US3402029

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:36

US3402029

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:36

US3402029

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:36

US3402029

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:36

US3402029

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:36

US3402029

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:36

US3402029

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:36

US3402029

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 21:41:36

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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)	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '16:30'	Tarin Gordon (b) (4) (b) (4)	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:30'	System	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Tarin Gordon (b) (4) (b) (4)	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 20:59:25

US3402029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:52

US3402029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24AUG2020 is recorded under Visit2 Day 29 visit in EDC, however the same is reported under Visit 2 Day 29 Visit with date 25AUG2020 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 06:37:08
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24AUG2020 is recorded under Visit2 Day 29 visit in EDC, however the same is reported under Visit 2 Day 29 Visit with date 25AUG2020 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 12:14:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24AUG2020 is recorded under Visit2 Day 29 visit in EDC, however the same is reported under Visit 2 Day 29 Visit with date 25AUG2020 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 11:33:15
User entered '24 Aug 2020'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:52

US3402029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '16:14'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:41:52

US3402029

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:14'	System	24 Aug 2020 21:41:52

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:22:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 21:05:59

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 21:05:59

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 21:05:59

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '16:11'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 21:05:59

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:22:31

[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 24AUG2020. However, collection date in GCL for the same visit is recorded as 25AUG2020. Please review and confirm the correct collection date. Thank you	(b) (4), (b) (6)	21 Oct 2020 09:46:33
' (Site from DM). User entered '24 Aug 2020 16:11'	System	25 Aug 2020 21:05:59

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 21:05:59

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 21:05:59

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	25 Aug 2020 21:05:59

US3402029

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 21:05:59

US3402029

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Aug 2020 21:42:01

US3402029

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 21:42:01

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:02:37', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '3aab1e5b-500b-467b-a287-00fc3bdb943c' User entered 'Yes (Y)'	System	24 Aug 2020 21:02:49

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:02:42', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '3aab1e5b-500b-467b-a287-00fc3bdb943c' User entered '97.9'	System	24 Aug 2020 21:02:49
	System	24 Aug 2020 21:02:49

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:02:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '3aab1e5b-500b-467b-a287-00fc3bdb943c'	System	24 Aug 2020 21:02:49
User entered 'No (N)'	System	24 Aug 2020 21:02:49

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:02:47', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '3aab1e5b-500b-467b-a287-00fc3bdb943c' User entered '24 Aug 2020 17:02'	System	24 Aug 2020 21:02:49
	System	24 Aug 2020 21:02:49

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:50'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 19:20'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:03:48', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2a14f63e-fc4b-4c7d-a4ad-a625da053d4d'	System	25 Aug 2020 10:04:04
User entered 'Yes (Y)'	System	25 Aug 2020 10:04:04

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:03:54', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2a14f63e-fc4b-4c7d-a4ad-a625da053d4d'	System	25 Aug 2020 10:04:04
User entered '98.8'	System	25 Aug 2020 10:04:04

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:03:57', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2a14f63e-fc4b-4c7d-a4ad-a625da053d4d'	System	25 Aug 2020 10:04:04
User entered 'No (N)'	System	25 Aug 2020 10:04:04

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:03:59', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2a14f63e-fc4b-4c7d-a4ad-a625da053d4d'	System	25 Aug 2020 10:04:04
User entered '25 Aug 2020 06:03'	System	25 Aug 2020 10:04:04

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 20:15'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 2'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T18:35:04', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'bcbcaa21-9cac-4d29-8f44-b6ff41ac346c'	System	25 Aug 2020 22:35:26
User entered 'Yes (Y)'	System	25 Aug 2020 22:35:26

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T18:35:08', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'bcbcaa21-9cac-4d29-8f44-b6ff41ac346c'	System	25 Aug 2020 22:35:26
User entered '98.8'	System	25 Aug 2020 22:35:26

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T18:35:10', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'bcbcaa21-9cac-4d29-8f44-b6ff41ac346c'	System	25 Aug 2020 22:35:26
User entered 'No (N)'	System	25 Aug 2020 22:35:26

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T18:35:12', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'bcbcaa21-9cac-4d29-8f44-b6ff41ac346c'	System	25 Aug 2020 22:35:26
User entered '25 Aug 2020 18:35'	System	25 Aug 2020 22:35:26

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 3'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:29', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '693930e2-d882-4713-b292-5f5e3f97b872'	System	26 Aug 2020 21:32:40
User entered 'Yes (Y)'	System	26 Aug 2020 21:32:40

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:32', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '693930e2-d882-4713-b292-5f5e3f97b872'	System	26 Aug 2020 21:32:40
User entered '98.2'	System	26 Aug 2020 21:32:40

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:34', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '693930e2-d882-4713-b292-5f5e3f97b872'	System	26 Aug 2020 21:32:40
User entered 'No (N)'	System	26 Aug 2020 21:32:40

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:36', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '693930e2-d882-4713-b292-5f5e3f97b872'	System	26 Aug 2020 21:32:40
User entered '26 Aug 2020 17:32'	System	26 Aug 2020 21:32:40

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 4'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:09', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deab5e32-8822-4f7b-8a6f-c4962d2276d9'	System	28 Aug 2020 03:12:22
User entered 'Yes (Y)'	System	28 Aug 2020 03:12:22

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:13', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deab5e32-8822-4f7b-8a6f-c4962d2276d9'	System	28 Aug 2020 03:12:22
User entered '99.1'	System	28 Aug 2020 03:12:22

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:15', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deab5e32-8822-4f7b-8a6f-c4962d2276d9'	System	28 Aug 2020 03:12:22
User entered 'No (N)'	System	28 Aug 2020 03:12:22

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:18', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deab5e32-8822-4f7b-8a6f-c4962d2276d9' User entered '27 Aug 2020 23:12'	System	28 Aug 2020 03:12:22

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 5'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:44:22', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '63b995a9-4589-41d6-879c-3611d57fc1cd'	System	29 Aug 2020 00:45:49
User entered 'Yes (Y)'	System	29 Aug 2020 00:45:49

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:45:39', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '63b995a9-4589-41d6-879c-3611d57fc1cd'	System	29 Aug 2020 00:45:49
User entered '98.9'	System	29 Aug 2020 00:45:49

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:45:43', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '63b995a9-4589-41d6-879c-3611d57fc1cd'	System	29 Aug 2020 00:45:49
User entered 'No (N)'	System	29 Aug 2020 00:45:49

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:45:45', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '63b995a9-4589-41d6-879c-3611d57fc1cd'	System	29 Aug 2020 00:45:49
User entered '28 Aug 2020 20:45'	System	29 Aug 2020 00:45:49

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 6'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:08', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '22526295-3bf3-400f-93a5-bf93e4c24844'	System	30 Aug 2020 03:42:17
User entered 'Yes (Y)'	System	30 Aug 2020 03:42:17

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:12', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '22526295-3bf3-400f-93a5-bf93e4c24844'	System	30 Aug 2020 03:42:17
User entered '98.6'	System	30 Aug 2020 03:42:17

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:14', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '22526295-3bf3-400f-93a5-bf93e4c24844'	System	30 Aug 2020 03:42:17
User entered 'No (N)'	System	30 Aug 2020 03:42:17

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:16', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '22526295-3bf3-400f-93a5-bf93e4c24844'	System	30 Aug 2020 03:42:17
User entered '29 Aug 2020 23:42'	System	30 Aug 2020 03:42:17

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 7'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:18:53', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '9c3104c1-649e-43ca-b694-717b2a34f883'	System	31 Aug 2020 01:19:07
User entered 'Yes (Y)'	System	31 Aug 2020 01:19:07

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:18:59', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '9c3104c1-649e-43ca-b694-717b2a34f883'	System	31 Aug 2020 01:19:07
User entered '98.6'	System	31 Aug 2020 01:19:07

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:19:01', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '9c3104c1-649e-43ca-b694-717b2a34f883'	System	31 Aug 2020 01:19:07
User entered 'No (N)'	System	31 Aug 2020 01:19:07

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:19:03', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '9c3104c1-649e-43ca-b694-717b2a34f883'	System	31 Aug 2020 01:19:07
User entered '30 Aug 2020 21:19'	System	31 Aug 2020 01:19:07

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:02:53', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'd71e6a27-7857-40cf-90f5-7aadc5c35e04'	System	24 Aug 2020 21:03:04
User entered 'None (1)'	System	24 Aug 2020 21:03:04

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:02:55', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'd71e6a27-7857-40cf-90f5-7aadc5c35e04'	System	24 Aug 2020 21:03:04
User entered 'No (N)'	System	24 Aug 2020 21:03:04

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:02:58', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'd71e6a27-7857-40cf-90f5-7aadc5c35e04'	System	24 Aug 2020 21:03:04
User entered 'No (N)'	System	24 Aug 2020 21:03:04

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:00', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'd71e6a27-7857-40cf-90f5-7aadc5c35e04'	System	24 Aug 2020 21:03:04
User entered 'None (1)'	System	24 Aug 2020 21:03:04

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:02', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'd71e6a27-7857-40cf-90f5-7aadc5c35e04'	System	24 Aug 2020 21:03:04
User entered '24 Aug 2020 17:03'	System	24 Aug 2020 21:03:04

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:50'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 19:20'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:09', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '9e211ba3-190b-487a-b409-4c8641531538'	System	25 Aug 2020 10:04:22
User entered 'None (1)'	System	25 Aug 2020 10:04:22

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:11', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '9e211ba3-190b-487a-b409-4c8641531538'	System	25 Aug 2020 10:04:22
User entered 'No (N)'	System	25 Aug 2020 10:04:22

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:14', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '9e211ba3-190b-487a-b409-4c8641531538'	System	25 Aug 2020 10:04:22
User entered 'No (N)'	System	25 Aug 2020 10:04:22

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:16', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '9e211ba3-190b-487a-b409-4c8641531538'	System	25 Aug 2020 10:04:22
User entered 'None (1)'	System	25 Aug 2020 10:04:22

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:20', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '9e211ba3-190b-487a-b409-4c8641531538'	System	25 Aug 2020 10:04:22
User entered '25 Aug 2020 06:04'	System	25 Aug 2020 10:04:22

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 20:15'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 2'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T18:35:15', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4156d7b6-3c60-43fc-9280-47e203a35756'	System	25 Aug 2020 22:35:29
User entered 'None (1)'	System	25 Aug 2020 22:35:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T18:35:17', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4156d7b6-3c60-43fc-9280-47e203a35756'	System	25 Aug 2020 22:35:29
User entered 'No (N)'	System	25 Aug 2020 22:35:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T18:35:19', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4156d7b6-3c60-43fc-9280-47e203a35756'	System	25 Aug 2020 22:35:29
User entered 'No (N)'	System	25 Aug 2020 22:35:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T18:35:20', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4156d7b6-3c60-43fc-9280-47e203a35756'	System	25 Aug 2020 22:35:29
User entered 'None (1)'	System	25 Aug 2020 22:35:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T18:35:23', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '4156d7b6-3c60-43fc-9280-47e203a35756'	System	25 Aug 2020 22:35:29
User entered '25 Aug 2020 18:35'	System	25 Aug 2020 22:35:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 3'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:39', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e348488a-4db9-4dc7-8f15-b7d7ab4fd6c9'	System	26 Aug 2020 21:32:49
User entered 'None (1)'	System	26 Aug 2020 21:32:49

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:41', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e348488a-4db9-4dc7-8f15-b7d7ab4fd6c9'	System	26 Aug 2020 21:32:49
User entered 'No (N)'	System	26 Aug 2020 21:32:49

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:42', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e348488a-4db9-4dc7-8f15-b7d7ab4fd6c9'	System	26 Aug 2020 21:32:49
User entered 'No (N)'	System	26 Aug 2020 21:32:49

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e348488a-4db9-4dc7-8f15-b7d7ab4fd6c9'	System	26 Aug 2020 21:32:49
User entered 'None (1)'	System	26 Aug 2020 21:32:49

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:46', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e348488a-4db9-4dc7-8f15-b7d7ab4fd6c9'	System	26 Aug 2020 21:32:49
User entered '26 Aug 2020 17:32'	System	26 Aug 2020 21:32:49

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 4'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:32', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '30456fbc-74e7-4953-965d-ba70a343a0a2'	System	28 Aug 2020 03:12:47
User entered 'None (1)'	System	28 Aug 2020 03:12:47

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:35', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '30456fbc-74e7-4953-965d-ba70a343a0a2'	System	28 Aug 2020 03:12:47
User entered 'No (N)'	System	28 Aug 2020 03:12:47

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:40', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '30456fbc-74e7-4953-965d-ba70a343a0a2'	System	28 Aug 2020 03:12:47
User entered 'No (N)'	System	28 Aug 2020 03:12:47

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:42', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '30456fbc-74e7-4953-965d-ba70a343a0a2'	System	28 Aug 2020 03:12:47
User entered 'None (1)'	System	28 Aug 2020 03:12:47

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '30456fbc-74e7-4953-965d-ba70a343a0a2'	System	28 Aug 2020 03:12:47
User entered '27 Aug 2020 23:12'	System	28 Aug 2020 03:12:47

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 5'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:45:49', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ccca3a48-4f91-4827-8c73-e416c9a6ce8a'	System	29 Aug 2020 00:46:09
User entered 'None (1)'	System	29 Aug 2020 00:46:09

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:45:52', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ccca3a48-4f91-4827-8c73-e416c9a6ce8a'	System	29 Aug 2020 00:46:09
User entered 'No (N)'	System	29 Aug 2020 00:46:09

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:01', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ccca3a48-4f91-4827-8c73-e416c9a6ce8a'	System	29 Aug 2020 00:46:09
User entered 'No (N)'	System	29 Aug 2020 00:46:09

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:04', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ccca3a48-4f91-4827-8c73-e416c9a6ce8a'	System	29 Aug 2020 00:46:09
User entered 'None (1)'	System	29 Aug 2020 00:46:09

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:08', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ccca3a48-4f91-4827-8c73-e416c9a6ce8a'	System	29 Aug 2020 00:46:09
User entered '28 Aug 2020 20:46'	System	29 Aug 2020 00:46:09

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 6'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:19', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e2920cbd-634d-42d7-bad3-7e23733b737d'	System	30 Aug 2020 03:42:29
User entered 'None (1)'	System	30 Aug 2020 03:42:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:22', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e2920cbd-634d-42d7-bad3-7e23733b737d'	System	30 Aug 2020 03:42:29
User entered 'No (N)'	System	30 Aug 2020 03:42:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:24', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e2920cbd-634d-42d7-bad3-7e23733b737d'	System	30 Aug 2020 03:42:29
User entered 'No (N)'	System	30 Aug 2020 03:42:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:25', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e2920cbd-634d-42d7-bad3-7e23733b737d'	System	30 Aug 2020 03:42:29
User entered 'None (1)'	System	30 Aug 2020 03:42:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:27', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e2920cbd-634d-42d7-bad3-7e23733b737d'	System	30 Aug 2020 03:42:29
User entered '29 Aug 2020 23:42'	System	30 Aug 2020 03:42:29

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 7'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:19:09', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '74614249-5972-4acb-a91f-e3d0a1588d93'	System	31 Aug 2020 01:19:26
User entered 'None (1)'	System	31 Aug 2020 01:19:26

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:19:11', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '74614249-5972-4acb-a91f-e3d0a1588d93'	System	31 Aug 2020 01:19:26
User entered 'No (N)'	System	31 Aug 2020 01:19:26

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:19:14', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '74614249-5972-4acb-a91f-e3d0a1588d93'	System	31 Aug 2020 01:19:26
User entered 'No (N)'	System	31 Aug 2020 01:19:26

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:19:15', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '74614249-5972-4acb-a91f-e3d0a1588d93'	System	31 Aug 2020 01:19:26
User entered 'None (1)'	System	31 Aug 2020 01:19:26

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:19:23', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '74614249-5972-4acb-a91f-e3d0a1588d93'	System	31 Aug 2020 01:19:26
User entered '30 Aug 2020 21:19'	System	31 Aug 2020 01:19:26

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:05', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2788ce91-e17a-4297-8912-ffb1743c749d'	System	24 Aug 2020 21:03:20
User entered 'None (0)'	System	24 Aug 2020 21:03:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:07', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2788ce91-e17a-4297-8912-ffb1743c749d'	System	24 Aug 2020 21:03:20
User entered 'None (0)'	System	24 Aug 2020 21:03:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:10', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2788ce91-e17a-4297-8912-ffb1743c749d'	System	24 Aug 2020 21:03:20
User entered 'None (0)'	System	24 Aug 2020 21:03:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:11', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2788ce91-e17a-4297-8912-ffb1743c749d'	System	24 Aug 2020 21:03:20
User entered 'None (0)'	System	24 Aug 2020 21:03:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:13', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2788ce91-e17a-4297-8912-ffb1743c749d'	System	24 Aug 2020 21:03:20
User entered 'None (0)'	System	24 Aug 2020 21:03:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:15', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2788ce91-e17a-4297-8912-ffb1743c749d'	System	24 Aug 2020 21:03:20
User entered 'None (0)'	System	24 Aug 2020 21:03:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:16', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2788ce91-e17a-4297-8912-ffb1743c749d'	System	24 Aug 2020 21:03:20
User entered 'No (N)'	System	24 Aug 2020 21:03:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-24T17:03:18', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2788ce91-e17a-4297-8912-ffb1743c749d'	System	24 Aug 2020 21:03:20
User entered '24 Aug 2020 17:03'	System	24 Aug 2020 21:03:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:50'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 19:20'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:27', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e15b2b68-d603-4b67-a559-cbb85876d97a'	System	25 Aug 2020 10:04:48
User entered 'None (0)'	System	25 Aug 2020 10:04:48

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:32', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e15b2b68-d603-4b67-a559-cbb85876d97a'	System	25 Aug 2020 10:04:48
User entered 'None (0)'	System	25 Aug 2020 10:04:48

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:34', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e15b2b68-d603-4b67-a559-cbb85876d97a'	System	25 Aug 2020 10:04:48
User entered 'None (0)'	System	25 Aug 2020 10:04:48

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:36', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e15b2b68-d603-4b67-a559-cbb85876d97a' User entered 'None (0)'	System	25 Aug 2020 10:04:48
	System	25 Aug 2020 10:04:48

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:38', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e15b2b68-d603-4b67-a559-cbb85876d97a'	System	25 Aug 2020 10:04:48
User entered 'None (0)'	System	25 Aug 2020 10:04:48

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:40', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e15b2b68-d603-4b67-a559-cbb85876d97a'	System	25 Aug 2020 10:04:48
User entered 'None (0)'	System	25 Aug 2020 10:04:48

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e15b2b68-d603-4b67-a559-cbb85876d97a'	System	25 Aug 2020 10:04:48
User entered 'No (N)'	System	25 Aug 2020 10:04:48

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T06:04:46', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e15b2b68-d603-4b67-a559-cbb85876d97a'	System	25 Aug 2020 10:04:48
User entered '25 Aug 2020 06:04'	System	25 Aug 2020 10:04:48

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 20:15'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 2'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T20:28:22', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'dd4b5be6-91b8-48f9-8881-2de8fc312856'	System	26 Aug 2020 00:28:54
User entered 'None (0)'	System	26 Aug 2020 00:28:54

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T20:28:28', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'dd4b5be6-91b8-48f9-8881-2de8fc312856'	System	26 Aug 2020 00:28:54
User entered 'None (0)'	System	26 Aug 2020 00:28:54

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T20:28:31', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'dd4b5be6-91b8-48f9-8881-2de8fc312856'	System	26 Aug 2020 00:28:54
User entered 'None (0)'	System	26 Aug 2020 00:28:54

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T20:28:35', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'dd4b5be6-91b8-48f9-8881-2de8fc312856'	System	26 Aug 2020 00:28:54
User entered 'None (0)'	System	26 Aug 2020 00:28:54

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T20:28:39', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'dd4b5be6-91b8-48f9-8881-2de8fc312856'	System	26 Aug 2020 00:28:54
User entered 'None (0)'	System	26 Aug 2020 00:28:54

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T20:28:40', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'dd4b5be6-91b8-48f9-8881-2de8fc312856'	System	26 Aug 2020 00:28:54
User entered 'None (0)'	System	26 Aug 2020 00:28:54

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T20:28:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'dd4b5be6-91b8-48f9-8881-2de8fc312856'	System	26 Aug 2020 00:28:54
User entered 'No (N)'	System	26 Aug 2020 00:28:54

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-25T20:28:51', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'dd4b5be6-91b8-48f9-8881-2de8fc312856'	System	26 Aug 2020 00:28:54
User entered '25 Aug 2020 20:28'	System	26 Aug 2020 00:28:54

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 3'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:49', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '18bde6ea-8fe0-4135-a18e-92c6328b8c98'	System	26 Aug 2020 21:33:01
User entered 'None (0)'	System	26 Aug 2020 21:33:01

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:50', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '18bde6ea-8fe0-4135-a18e-92c6328b8c98'	System	26 Aug 2020 21:33:01
User entered 'None (0)'	System	26 Aug 2020 21:33:01

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:52', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '18bde6ea-8fe0-4135-a18e-92c6328b8c98'	System	26 Aug 2020 21:33:01
User entered 'None (0)'	System	26 Aug 2020 21:33:01

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:53', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '18bde6ea-8fe0-4135-a18e-92c6328b8c98'	System	26 Aug 2020 21:33:01
User entered 'None (0)'	System	26 Aug 2020 21:33:01

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:54', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '18bde6ea-8fe0-4135-a18e-92c6328b8c98'	System	26 Aug 2020 21:33:01
User entered 'None (0)'	System	26 Aug 2020 21:33:01

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:55', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '18bde6ea-8fe0-4135-a18e-92c6328b8c98'	System	26 Aug 2020 21:33:01
User entered 'None (0)'	System	26 Aug 2020 21:33:01

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:57', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '18bde6ea-8fe0-4135-a18e-92c6328b8c98'	System	26 Aug 2020 21:33:01
User entered 'No (N)'	System	26 Aug 2020 21:33:01

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-26T17:32:58', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '18bde6ea-8fe0-4135-a18e-92c6328b8c98'	System	26 Aug 2020 21:33:01
User entered '26 Aug 2020 17:32'	System	26 Aug 2020 21:33:01

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 4'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:49', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '7dfaed2d-1c94-4379-bd7b-494146269d38'	System	28 Aug 2020 03:13:09
User entered 'None (0)'	System	28 Aug 2020 03:13:09

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:54', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '7dfaed2d-1c94-4379-bd7b-494146269d38'	System	28 Aug 2020 03:13:09
User entered 'None (0)'	System	28 Aug 2020 03:13:09

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:58', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '7dfaed2d-1c94-4379-bd7b-494146269d38'	System	28 Aug 2020 03:13:09
User entered 'None (0)'	System	28 Aug 2020 03:13:09

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:12:59', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '7dfaed2d-1c94-4379-bd7b-494146269d38'	System	28 Aug 2020 03:13:09
User entered 'None (0)'	System	28 Aug 2020 03:13:09

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:13:01', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '7dfaed2d-1c94-4379-bd7b-494146269d38'	System	28 Aug 2020 03:13:09
User entered 'None (0)'	System	28 Aug 2020 03:13:09

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:13:02', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '7dfaed2d-1c94-4379-bd7b-494146269d38'	System	28 Aug 2020 03:13:09
User entered 'None (0)'	System	28 Aug 2020 03:13:09

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:13:05', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '7dfaed2d-1c94-4379-bd7b-494146269d38'	System	28 Aug 2020 03:13:09
User entered 'No (N)'	System	28 Aug 2020 03:13:09

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-27T23:13:07', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '7dfaed2d-1c94-4379-bd7b-494146269d38'	System	28 Aug 2020 03:13:09
User entered '27 Aug 2020 23:13'	System	28 Aug 2020 03:13:09

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 5'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:13', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e3819ad5-0c08-488a-8905-b873039e063f'	System	29 Aug 2020 00:46:39
User entered 'None (0)'	System	29 Aug 2020 00:46:39

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:16', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e3819ad5-0c08-488a-8905-b873039e063f'	System	29 Aug 2020 00:46:39
User entered 'None (0)'	System	29 Aug 2020 00:46:39

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:20', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e3819ad5-0c08-488a-8905-b873039e063f'	System	29 Aug 2020 00:46:39
User entered 'None (0)'	System	29 Aug 2020 00:46:39

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:22', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e3819ad5-0c08-488a-8905-b873039e063f'	System	29 Aug 2020 00:46:39
User entered 'None (0)'	System	29 Aug 2020 00:46:39

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:26', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e3819ad5-0c08-488a-8905-b873039e063f'	System	29 Aug 2020 00:46:39
User entered 'None (0)'	System	29 Aug 2020 00:46:39

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:28', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e3819ad5-0c08-488a-8905-b873039e063f'	System	29 Aug 2020 00:46:39
User entered 'None (0)'	System	29 Aug 2020 00:46:39

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:30', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e3819ad5-0c08-488a-8905-b873039e063f'	System	29 Aug 2020 00:46:39
User entered 'No (N)'	System	29 Aug 2020 00:46:39

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-28T20:46:36', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'e3819ad5-0c08-488a-8905-b873039e063f'	System	29 Aug 2020 00:46:39
User entered '28 Aug 2020 20:46'	System	29 Aug 2020 00:46:39

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 6'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:31', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deb8faf6-490a-4d2c-bd91-1f4037095bf4'	System	30 Aug 2020 03:42:45
User entered 'None (0)'	System	30 Aug 2020 03:42:45

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:32', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deb8faf6-490a-4d2c-bd91-1f4037095bf4'	System	30 Aug 2020 03:42:45
User entered 'None (0)'	System	30 Aug 2020 03:42:45

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:33', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deb8faf6-490a-4d2c-bd91-1f4037095bf4'	System	30 Aug 2020 03:42:45
User entered 'None (0)'	System	30 Aug 2020 03:42:45

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:35', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deb8faf6-490a-4d2c-bd91-1f4037095bf4' User entered 'None (0)'	System	30 Aug 2020 03:42:45
	System	30 Aug 2020 03:42:45

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:36', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deb8faf6-490a-4d2c-bd91-1f4037095bf4'	System	30 Aug 2020 03:42:45
User entered 'None (0)'	System	30 Aug 2020 03:42:45

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:37', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deb8faf6-490a-4d2c-bd91-1f4037095bf4'	System	30 Aug 2020 03:42:45
User entered 'None (0)'	System	30 Aug 2020 03:42:45

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:39', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deb8faf6-490a-4d2c-bd91-1f4037095bf4'	System	30 Aug 2020 03:42:45
User entered 'No (N)'	System	30 Aug 2020 03:42:45

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-29T23:42:41', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'deb8faf6-490a-4d2c-bd91-1f4037095bf4'	System	30 Aug 2020 03:42:45
User entered '29 Aug 2020 23:42'	System	30 Aug 2020 03:42:45

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 20:59:25
User entered 'Day 7'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:20:04', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '33afcaec-6822-46d2-a301-cf1bb6f5dd08'	System	31 Aug 2020 01:20:20
User entered 'None (0)'	System	31 Aug 2020 01:20:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:20:07', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '33afcaec-6822-46d2-a301-cf1bb6f5dd08'	System	31 Aug 2020 01:20:20
User entered 'None (0)'	System	31 Aug 2020 01:20:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:20:09', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '33afcaec-6822-46d2-a301-cf1bb6f5dd08'	System	31 Aug 2020 01:20:20
User entered 'None (0)'	System	31 Aug 2020 01:20:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:20:10', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '33afcaec-6822-46d2-a301-cf1bb6f5dd08'	System	31 Aug 2020 01:20:20
User entered 'None (0)'	System	31 Aug 2020 01:20:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:20:12', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '33afcaec-6822-46d2-a301-cf1bb6f5dd08'	System	31 Aug 2020 01:20:20
User entered 'None (0)'	System	31 Aug 2020 01:20:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:20:13', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '33afcaec-6822-46d2-a301-cf1bb6f5dd08'	System	31 Aug 2020 01:20:20
User entered 'None (0)'	System	31 Aug 2020 01:20:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:20:15', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '33afcaec-6822-46d2-a301-cf1bb6f5dd08'	System	31 Aug 2020 01:20:20
User entered 'No (N)'	System	31 Aug 2020 01:20:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-08-30T21:20:17', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '33afcaec-6822-46d2-a301-cf1bb6f5dd08'	System	31 Aug 2020 01:20:20
User entered '30 Aug 2020 21:20'	System	31 Aug 2020 01:20:20

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 20:59:25

US3402029

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:22:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 20:59:25

US3402029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 12:57:13

US3402029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 12:57:13

US3402029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[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)	01 Sep 2020 12:57:13

US3402029

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	01 Sep 2020 12:57:13

US3402029

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	01 Sep 2020 12:57:18

US3402029

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 12:57:18

US3402029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:27:42

US3402029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '07 Sep 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:04:26
User entered '7 Sep 2020'	Traci Hull (b) (4)	15 Sep 2020 11:27:42

US3402029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[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)	15 Sep 2020 11:27:42

US3402029

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:27:42

US3402029

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:27:46

US3402029

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 11:27:46

US3402029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:27:58

US3402029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:27:58

US3402029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[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)	15 Sep 2020 11:27:58

US3402029

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:27:58

US3402029

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	15 Sep 2020 11:29:27

US3402029

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 11:29:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	18 Sep 2020 14:30:27
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	18 Sep 2020 14:30:15
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:30:15

US3402029

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '18 Sep 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	18 Sep 2020 14:30:27
User entered empty.	Traci Hull (b) (4)	18 Sep 2020 14:30:15

US3402029

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[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)	18 Sep 2020 14:30:15

US3402029

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	18 Sep 2020 14:30:15

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '10:06'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 10:06'	System	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '92'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '15'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '120'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	18 Sep 2020 14:31:27

US3402029

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	18 Sep 2020 14:32:46
Comment added 'NO SYMPTOMS. PHYSICAL EXAM NOT REQUIRED'.	Traci Hull (b) (4)	18 Sep 2020 14:32:16
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	(b) (4)	
User entered 'No (N)'	System	18 Sep 2020 14:31:41
	Traci Hull (b) (4)	18 Sep 2020 14:31:41
	(b) (4)	

US3402029

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Traci Hull (b) (4)	18 Sep 2020 14:32:46
User entered '18 Sep 2020'	Traci Hull (b) (4)	18 Sep 2020 14:31:41

US3402029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:33:12

US3402029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:33:12

US3402029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '10:15'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:33:12

US3402029

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '18 Sep 2020 10:15'	System	18 Sep 2020 14:33:12

US3402029

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	18 Sep 2020 14:33:16

US3402029

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 14:33:16

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 64'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-09-26T00:02:14', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ad96d984-1f1e-415d-ba8a-8d9c788a54e2'	System	26 Sep 2020 04:02:56
User entered 'No (N)'	System	26 Sep 2020 04:02:56

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with 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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-09-26T00:02:40', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ad96d984-1f1e-415d-ba8a-8d9c788a54e2'	System	26 Sep 2020 04:02:56
User entered 'No (N)'	System	26 Sep 2020 04:02:56

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-09-26T00:02:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'ad96d984-1f1e-415d-ba8a-8d9c788a54e2' User entered '26 Sep 2020 00:02:44'	System	26 Sep 2020 04:02:56
	System	26 Sep 2020 04:02:56

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '26 Sep 2020 00:01'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '30 Sep 2020 23:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 71'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-05T17:47:38', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'fda6381b-414d-49d7-b225-2e54f5c24d18'	System	05 Oct 2020 21:47:47
User entered 'No (N)'	System	05 Oct 2020 21:47:47

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with 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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-05T17:47:44', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'fda6381b-414d-49d7-b225-2e54f5c24d18'	System	05 Oct 2020 21:47:47
User entered 'No (N)'	System	05 Oct 2020 21:47:47

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-05T17:47:46', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'fda6381b-414d-49d7-b225-2e54f5c24d18' User entered '05 Oct 2020 17:47:46'	System	05 Oct 2020 21:47:47
	System	05 Oct 2020 21:47:47

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '03 Oct 2020 00:01'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '07 Oct 2020 23:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 78'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-10T00:01:22', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '21fdcc25-5401-4c1d-b435-289d88a1dd36' User entered 'No (N)'	System	10 Oct 2020 04:01:32
	System	10 Oct 2020 04:01:32

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with 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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-10T00:01:26', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '21fdcc25-5401-4c1d-b435-289d88a1dd36'	System	10 Oct 2020 04:01:32
User entered 'No (N)'	System	10 Oct 2020 04:01:32

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-10T00:01:29', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '21fdcc25-5401-4c1d-b435-289d88a1dd36' User entered '10 Oct 2020 00:01:29'	System	10 Oct 2020 04:01:32
	System	10 Oct 2020 04:01:32

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '10 Oct 2020 00:01'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '14 Oct 2020 23:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 92'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-26T13:29:06', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2af70591-972b-42a9-bcf7-355f4ecc352a' User entered 'No (N)'	System	26 Oct 2020 17:29:14
	System	26 Oct 2020 17:29:14

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with 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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-26T13:29:08', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2af70591-972b-42a9-bcf7-355f4ecc352a'	System	26 Oct 2020 17:29:14
User entered 'No (N)'	System	26 Oct 2020 17:29:14

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-26T13:29:11', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '2af70591-972b-42a9-bcf7-355f4ecc352a' User entered '26 Oct 2020 13:29:11'	System	26 Oct 2020 17:29:14
	System	26 Oct 2020 17:29:14

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '24 Oct 2020 00:01'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '28 Oct 2020 23:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 99'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-31T23:55:11', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '65f5eae9-4066-4103-a454-4be2c59a2b54'	System	01 Nov 2020 03:55:20
User entered 'No (N)'	System	01 Nov 2020 03:55:20

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with 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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-31T23:55:14', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '65f5eae9-4066-4103-a454-4be2c59a2b54'	System	01 Nov 2020 03:55:20
User entered 'No (N)'	System	01 Nov 2020 03:55:20

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-10-31T23:55:16', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '65f5eae9-4066-4103-a454-4be2c59a2b54' User entered '31 Oct 2020 23:55:16'	System	01 Nov 2020 03:55:20
	System	01 Nov 2020 03:55:20

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '31 Oct 2020 00:01'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '04 Nov 2020 23:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 106'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-11-08T09:00:18', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b336d62a-409e-4fed-afbe-6eba641ce459'	System	08 Nov 2020 14:00:25
User entered 'No (N)'	System	08 Nov 2020 14:00:25

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with 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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-11-08T09:00:21', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b336d62a-409e-4fed-afbe-6eba641ce459'	System	08 Nov 2020 14:00:25
User entered 'No (N)'	System	08 Nov 2020 14:00:25

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-11-08T09:00:23', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: 'b336d62a-409e-4fed-afbe-6eba641ce459'	System	08 Nov 2020 14:00:25
User entered '08 Nov 2020 09:00:23'	System	08 Nov 2020 14:00:25

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '07 Nov 2020 00:01'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '11 Nov 2020 23:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered 'Day 113'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-11-14T21:07:17', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '60975262-5826-4d1c-840b-a5850f926fac'	System	15 Nov 2020 02:07:36
User entered 'No (N)'	System	15 Nov 2020 02:07:36

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

Have you been exposed to someone with 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 (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-11-14T21:07:31', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '60975262-5826-4d1c-840b-a5850f926fac'	System	15 Nov 2020 02:07:36
User entered 'No (N)'	System	15 Nov 2020 02:07:36

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18173304-4088-417F-AA1C-F1012A2B600A)', Time: '2020-11-14T21:07:33', User OID: 'PatientReportedOutcome (US3402029)', ODM File OID: '60975262-5826-4d1c-840b-a5850f926fac' User entered '14 Nov 2020 21:07:33'	System	15 Nov 2020 02:07:36
	System	15 Nov 2020 02:07:36

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '14 Nov 2020 00:01'	System	27 Jul 2020 21:22:51

US3402029

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	27 Jul 2020 21:22:51
User entered '18 Nov 2020 23:59'	System	27 Jul 2020 21:22:51

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '23 Sep 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '27 Sep 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '30 Sep 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '04 Oct 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '07 Oct 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '11 Oct 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '14 Oct 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '18 Oct 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '21 Oct 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '25 Oct 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '28 Oct 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '01 Nov 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '04 Nov 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '08 Nov 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '11 Nov 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '15 Nov 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:13:20

US3402029

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:22:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:13:20
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:13:20

US3402029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	24 Nov 2020 17:22:46
Comment added 'SUBJECT IN CONVALESCENT PHASE'.	Traci Hull (b) (4)	24 Nov 2020 14:39:36
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 14:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 14:39:10
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	24 Nov 2020 14:39:10
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	24 Nov 2020 14:39:10
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 14:38:45
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	24 Nov 2020 14:38:45
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4)	24 Nov 2020 14:38:45
Comment added 'subject in convalescent phase'.	Traci Hull (b) (4)	24 Nov 2020 12:09:10
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	24 Nov 2020 12:08:43
User entered 'No (N)'	Traci Hull (b) (4)	24 Nov 2020 12:08:43

US3402029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:08:43

US3402029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Jennifer Molstead (b) (4)	24 Nov 2020 17:22:46
User entered 'Contact Not Made (CONTACT NOT MADE)'	Traci Hull (b) (4)	24 Nov 2020 12:08:43

US3402029

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Comment added 'CONTACT NOT MADE DUE TO SUBJECT BEING IN CONVALESCENT PHASE'.	Traci Hull (b) (4)	24 Nov 2020 16:00:31
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	24 Nov 2020 12:09:40
Please review and reconcile.' (Site from System).		
User entered 'subject in convalescent phase' reason for change: Per Query Resolution	Traci Hull (b) (4)	24 Nov 2020 12:09:40
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	24 Nov 2020 12:08:43
Please review and reconcile.' (Site from System).		
User entered empty.	Traci Hull (b) (4)	24 Nov 2020 12:08:43

US3402029

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:10:03

US3402029

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 12:10:03

US3402029

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:10:21

US3402029

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:10:21

US3402029

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[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)	24 Nov 2020 12:10:21

US3402029

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:22:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:10:21

US3402029

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	24 Nov 2020 12:10:30

US3402029

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:22:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 12:10:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:22:31

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:43
User closed query 'Per ETRTR: Please complete data entry within Illness Visit Folder, including Saliva collection entries, thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 00:18:49
Query 'Per ETRTR: Please complete data entry within Illness Visit Folder, including Saliva collection entries, thanks.' answered with 'UPDATED' (Site from CRA).	Traci Hull (b) (4)	16 Oct 2020 18:01:58
User entered '30 Sep 2020' reason for change: Per Query Resolution	(b) (4)	16 Oct 2020 18:01:51
User opened query 'Per ETRTR: Please complete data entry within Illness Visit Folder, including Saliva collection entries, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 16:22:30
User entered '29 Sep 2020'	Traci Hull (b) (4)	30 Sep 2020 17:34:08

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:22:31

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:43
User entered '12:45'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:34:08

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:22:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:45'	System	16 Oct 2020 18:01:51
User entered '29 Sep 2020 12:45'	System	30 Sep 2020 17:34:08

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:22:31

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:43
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:34:08

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:22:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:27:43
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:34:08

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User closed query 'Per source, Day 1 of symptom was 29-SEP-20. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:51:05
Query 'Per source, Day 1 of symptom was 29-SEP-20. Please review and update entries.' answered with 'Updated' (Site from CRA).	Jennifer Molstead (b) (4)	02 Nov 2020 20:35:20
User opened query 'Per source, Day 1 of symptom was 29-SEP-20. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:29:06
User entered 'Day 1 (Day 1)'	Traci Hull (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 21:51:07
DataPoint Un-verified.	Jennifer Molstead (b) (4)	02 Nov 2020 20:35:13
	(b) (4)	
User entered '29 Sep 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	02 Nov 2020 20:35:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '30 Sep 2020'	Traci Hull (b) (4)	30 Sep 2020 17:35:15
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	30 Sep 2020 17:35:15
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.1' F	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	30 Sep 2020 17:35:15
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	30 Sep 2020 17:35:15

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 2 (Day 2)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:31:59
User closed query 'Per EDC Day 1 of symptoms was 29 Sep 2020 - Day 2 should be 30 Sep 2020. Please verify and update chronologically for all the other days. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:31:58
Query 'Per EDC Day 1 of symptoms was 29 Sep 2020 - Day 2 should be 30 Sep 2020. Please verify and update chronologically for all the other days. ' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	23 Nov 2020 19:13:06
User opened query 'Per EDC Day 1 of symptoms was 29 Sep 2020 - Day 2 should be 30 Sep 2020. Please verify and update chronologically for all the other days. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:26:04
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 18:24:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:23:59
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:13:35
User entered '01 Oct 2020' reason for change: Data Entry Error	Traci Hull (b) (4)	11 Nov 2020 12:13:35
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '1 Oct 2020'	Traci Hull (b) (4)	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '99'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '100.5' F	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Oct 2020 14:43:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	02 Oct 2020 14:43:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 3 (Day 3)'	Traci Hull (b) (4)	05 Oct 2020 15:10:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:13:49
	(b) (4)	
User entered '02 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:13:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '2 Oct 2020'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Oct 2020 15:10:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '101.0' F	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 15:10:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 15:10:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 15:10:21

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 15:10:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 15:10:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 15:10:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 15:10:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 15:10:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Oct 2020 15:10:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	05 Oct 2020 15:10:21
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 4 (Day 4)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01

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Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:14:06
	(b) (4)	
User entered '03 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:14:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '3 Oct 2020'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '94'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	06 Oct 2020 11:49:01

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '102.0' F	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 11:49:01

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 11:49:01

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 11:49:01

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 11:49:01

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 11:49:01

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 11:49:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 11:49:01

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 5 (Day 5)'	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:14:32
	(b) (4)	
User entered '04 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:14:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '4 Oct 2020'	Traci Hull (b) (4)	06 Oct 2020 11:50:17
	(b) (4)	

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Form: Symptom Log (5)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	06 Oct 2020 11:50:17
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '94' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	06 Oct 2020 12:04:50
User entered empty.	System	06 Oct 2020 11:50:17

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Form: Symptom Log (5)

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[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.9' F reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Form: Symptom Log (5)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: Data Entry Error	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Form: Symptom Log (5)

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[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	06 Oct 2020 12:04:50
User entered empty.	Traci Hull (b) (4)	06 Oct 2020 11:50:17

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 6 (Day 6)'	Traci Hull (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:14:44
	(b) (4)	
User entered '05 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:14:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '5 Oct 2020'	Traci Hull (b) (4)	06 Oct 2020 12:05:37
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	06 Oct 2020 12:05:37
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '93'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 12:05:37
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 12:05:37
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 12:05:37
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 12:05:37
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 12:05:37
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 12:05:37
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	06 Oct 2020 12:05:37
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	06 Oct 2020 12:05:37

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 7 (Day 7)'	Traci Hull (b) (4)	07 Oct 2020 13:26:35

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:14:56
	(b) (4)	
User entered '06 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:14:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '6 Oct 2020'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '92'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	07 Oct 2020 13:26:35

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.7' F	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:26:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:26:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:26:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:26:35

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:26:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:26:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:26:35

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:26:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:26:35

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Form: Symptom Log (7)

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[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	07 Oct 2020 13:26:35
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 8 (Day 8)'	Traci Hull (b) (4)	09 Oct 2020 13:43:24

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:15:14
	(b) (4)	
User entered '07 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:15:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '7 Oct 2020'	Traci Hull (b) (4)	09 Oct 2020 13:43:24
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	09 Oct 2020 13:43:24
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '88'	Traci Hull (b) (4)	09 Oct 2020 13:43:24
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Oct 2020 13:43:24

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '101.0' F	Traci Hull (b) (4)	09 Oct 2020 13:43:24
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Moderate (Moderate)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	09 Oct 2020 13:43:24
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Moderate (Moderate)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	09 Oct 2020 13:43:24
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

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Form: Symptom Log (8)

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[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)' reason for change: New Information	Traci Hull (b) (4)	09 Oct 2020 13:45:10
User entered empty.	Traci Hull (b) (4)	09 Oct 2020 13:43:24

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 13:45:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:15:29
	(b) (4)	
User entered '08 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:15:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '8 Oct 2020'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 13:45:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '83'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 13:45:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Oct 2020 13:45:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '101.4' F	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 13:45:58

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 13:45:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 13:45:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	09 Oct 2020 13:45:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Moderate (Moderate)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	09 Oct 2020 13:45:58
	(b) (4)	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 10 (Day 10)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Traci Hull (b) (4)	11 Nov 2020 12:15:44
	(b) (4)	
User entered '09 Oct 2020' reason for change: New Information	Traci Hull (b) (4)	11 Nov 2020 12:15:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '9 Oct 2020'	Traci Hull (b) (4)	12 Oct 2020 18:01:18
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	12 Oct 2020 18:01:18
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '88'	Traci Hull (b) (4)	12 Oct 2020 18:01:18
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:01:18
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:01:18
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:01:18
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:01:18
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:01:18
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:01:18

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:01:18
	(b) (4)	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 11 (Day 11)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '10 Oct 2020'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '92'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 18:02:01

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.8' F	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:01

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:01
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 12 (Day 12)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '11 Oct 2020'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '94'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Oct 2020 18:02:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.9' F	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	12 Oct 2020 18:02:30

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	12 Oct 2020 18:02:30
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 13 (Day 13)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '12 Oct 2020'	Traci Hull (b) (4)	14 Oct 2020 13:23:23
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	14 Oct 2020 13:23:23
	(b) (4)	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '93'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Oct 2020 13:23:23

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.2' F	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:23:23
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:23:23
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:23:23
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:23:23
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:23:23
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:23:23

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:23:23
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '13 Oct 2020'	Traci Hull (b) (4)	14 Oct 2020 13:24:10
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Oct 2020 13:24:10

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.0' F	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:24:10
	(b) (4)	

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:24:10
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Form: Symptom Log (14)

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[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:24:10
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:24:10
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:24:10
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:24:10

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:24:10
	(b) (4)	

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	14 Oct 2020 13:24:10
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 15 (Day 15)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '14 Oct 2020'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	15 Oct 2020 12:07:09
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	15 Oct 2020 12:07:09

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Form: Symptom Log (15)

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[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.0' F	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	15 Oct 2020 12:07:09
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	15 Oct 2020 12:07:09
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	15 Oct 2020 12:07:09
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	15 Oct 2020 12:07:09
	(b) (4)	

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	15 Oct 2020 12:07:09
	(b) (4)	

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Form: Symptom Log (15)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	15 Oct 2020 12:07:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (15)

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[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	15 Oct 2020 12:07:09
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (16)

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[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 17 (Day 17)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 16 (Day 16)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '15 Oct 2020'	Traci Hull (b) (4)	16 Oct 2020 11:50:35
	(b) (4)	

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Form: Symptom Log (16)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	16 Oct 2020 11:50:35
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.2' F	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:50:35
	(b) (4)	

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Form: Symptom Log (16)

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[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:50:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:50:35
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:50:35
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (16)

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[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	16 Oct 2020 11:50:35
	(b) (4)	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	16 Oct 2020 11:50:35

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Form: Symptom Log (17)

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[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 18 (Day 18)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 17 (Day 17)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:30:55

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '16 Oct 2020'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

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Form: Symptom Log (17)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Oct 2020 13:30:55

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.2' F	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:30:55

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

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[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

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Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:30:55

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:30:55

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:30:55

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:30:55

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:30:55

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:30:55

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:30:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 18 (Day 18)'	Traci Hull (b) (4)	20 Oct 2020 13:31:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '17 Oct 2020'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Oct 2020 13:31:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.0' F	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:31:49
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:31:49
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:31:49
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:31:49
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:31:49
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:31:49
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:31:49
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:31:49
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:31:49

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 20 (Day 20)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 19 (Day 19)'	Traci Hull (b) (4)	20 Oct 2020 13:32:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '18 Oct 2020'	Traci Hull (b) (4)	20 Oct 2020 13:32:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	20 Oct 2020 13:32:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4)	20 Oct 2020 13:32:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Oct 2020 13:32:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.0' F	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:16
	(b) (4)	

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Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:16
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:16

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:16
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 21 (Day 21)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 20 (Day 20)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 27OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 14:09:27
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 27OCT2020. Please reconcile or clarify.' answered with 'Subject had no symptoms. Subject came in for day 28 convalescent visit. ' (Site from DM).	Jennifer Molstead (b) (4)	09 Nov 2020 23:08:48
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 27OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:55:19
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '19 Oct 2020'	Traci Hull (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:46
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:46
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:46
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	20 Oct 2020 13:32:46
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (20)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	20 Oct 2020 13:32:46

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 22 (Day 22)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '20 Oct 2020'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.3' F	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	21 Oct 2020 11:36:14
	(b) (4)	

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Form: Symptom Log (21)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Oct 2020 11:36:14

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 23 (Day 23)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 22 (Day 22)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

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Form: Symptom Log (22)

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '21 Oct 2020'	Traci Hull (b) (4)	22 Oct 2020 11:37:30
	(b) (4)	

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Form: Symptom Log (22)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	22 Oct 2020 11:37:30
	(b) (4)	

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Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

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Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Oct 2020 11:37:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.2' F	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:37:30
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	22 Oct 2020 11:37:30
	(b) (4)	

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Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

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Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

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Form: Symptom Log (22)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	22 Oct 2020 11:37:30

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 24 (Day 24)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 23 (Day 23)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '22 Oct 2020'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	26 Oct 2020 12:09:38
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4)	26 Oct 2020 12:09:38
	(b) (4)	

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Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Oct 2020 12:09:38

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.0' F	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:09:38
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:09:38
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:09:38
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:09:38
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:09:38

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (23)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:09:38
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 25 (Day 25)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 24 (Day 24)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '23 Oct 2020'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	26 Oct 2020 12:10:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Oct 2020 12:10:35

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Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.1' F	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:10:35
	(b) (4)	

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Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:10:35
	(b) (4)	

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Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:10:35
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (24)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:10:35

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 26 (Day 26)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 25 (Day 25)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '24 Oct 2020'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Oct 2020 12:11:13

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Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.2' F	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:11:13
	(b) (4)	

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Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:11:13
	(b) (4)	

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Form: Symptom Log (25)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:11:13
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:11:13
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:11:13
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:11:13
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (25)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:13

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 27 (Day 27)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 26 (Day 26)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '25 Oct 2020'	Traci Hull (b) (4)	26 Oct 2020 12:11:43
	(b) (4)	

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Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '97.5' F	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:11:43
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 12:11:43
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (26)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 12:11:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 28 (Day 28)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 27 (Day 27)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '26 Oct 2020'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	26 Oct 2020 20:17:47

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98.9' F	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	26 Oct 2020 20:17:47
	(b) (4)	

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Form: Symptom Log (27)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	26 Oct 2020 20:17:47

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Form: Symptom Log (28)

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[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 29 (Day 29)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	23 Nov 2020 19:07:09
User entered 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 13:59:51

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[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '27 Oct 2020'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '0'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

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[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '98'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	27 Oct 2020 13:59:51

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Form: Symptom Log (28)

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[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered '36.8' C	Traci Hull (b) (4) (b) (4)	27 Oct 2020 13:59:51

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 13:59:51

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 13:59:51

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 13:59:51

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 13:59:51

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 13:59:51

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 13:59:51

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Oct 2020 13:59:51

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Form: Symptom Log (28)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:29:41
User entered 'None (None)'	Traci Hull (b) (4)	27 Oct 2020 13:59:51
	(b) (4)	

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Form: Symptom Log (29)

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[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

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[Date](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

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Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

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Form: Symptom Log (29)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 19:09:55

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.1' F	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

Fatigue

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (29)

Generated On: 26 Nov 2020 09:22:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jennifer Molstead (b) (4)	23 Nov 2020 19:09:55
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:22:31

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:30:12
User closed query 'Please verify as date doesn't match contact date.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 04:34:56
Query 'Please verify as date doesn't match contact date.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	28 Oct 2020 13:38:34
User entered '30 Sep 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	28 Oct 2020 13:38:26
User opened query 'Please verify as date doesn't match contact date.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 00:19:52
User entered '29 Sep 2020'	Jennifer Molstead (b) (4)	03 Oct 2020 19:05:54

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Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:22:31

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:30:12
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:05:54

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:22:31

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:30:12
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)	06 Oct 2020 09:13:30
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 'Correct as is' (Site from System).	Jennifer Molstead (b) (4)	03 Oct 2020 19:06:10
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	03 Oct 2020 19:05:54
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:05:54

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:22:31

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:30:12
User closed query 'Please verify as test date doesn't match lab results with collection date of 30Sep20' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 04:34:58
Query 'Please verify as test date doesn't match lab results with collection date of 30Sep20' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	28 Oct 2020 13:38:40
User entered '30 Sep 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	28 Oct 2020 13:38:26
User opened query 'Please verify as test date doesn't match lab results with collection date of 30Sep20' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 00:20:19
User entered '29 Sep 2020'	Jennifer Molstead (b) (4)	03 Oct 2020 19:05:54

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Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:30:12
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:05:54

US3402029

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:22:31

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:30:12
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:05:54
	(b) (4)	

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Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:22:31

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:30:12
User entered 'No (N)' reason for change: New Information	Traci Hull (b) (4)	14 Oct 2020 13:25:38
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:05:54

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:22:31

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:30:12
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 13:25:38
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Oct 2020 19:05:54
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:05:54

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:22:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:30:12
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 13:25:38
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Oct 2020 19:05:54
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:05:54

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 19:05:54

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered 'No (N)' reason for change: Per Query Resolution	Abigail Wine (b) (4)	29 Oct 2020 21:30:10
User entered 'Yes (Y)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Oct 2020 18:01:11
User entered 'No (N)'	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[Start Date](#)

Audit	User	Time (GMT)
User closed query 'Please verify as NO has been reported for RR>= 30 but you have entered a start date for that event. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:57:07
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
Query 'Please verify as NO has been reported for RR>= 30 but you have entered a start date for that event. Please reconcile.' answered with 'updated' (Site from CRA).	Jennifer Molstead (b) (4)	30 Oct 2020 10:39:06
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4)	30 Oct 2020 10:38:59
User opened query 'Please verify as NO has been reported for RR>= 30 but you have entered a start date for that event. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 00:55:33
User closed query 'If previous question is answered as "YES" the following fields are to be completed. Please verify and enter data.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 00:54:52
Query 'If previous question is answered as "YES" the following fields are to be completed. Please verify and enter data.' answered with 'resolved per query resolution' (Site from CRA).	Abigail Wine (b) (4)	29 Oct 2020 21:30:40
User entered '30 Sep 2020' reason for change: Per Query Resolution	Abigail Wine (b) (4)	29 Oct 2020 21:26:38
User opened query 'If previous question is answered as "YES" the following fields are to be completed. Please verify and enter data.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:13:12
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered 'No (N)' reason for change: Per Query Resolution	Abigail Wine (b) (4)	29 Oct 2020 21:30:27
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	16 Oct 2020 18:01:11
User entered 'Yes (Y)' reason for change: Per Query Resolution	System	16 Oct 2020 18:01:11
User opened query 'Data is required. Please complete.' (Site from System).	Traci Hull (b) (4)	16 Oct 2020 18:01:11
User entered empty.	(b) (4)	
	System	14 Oct 2020 13:31:05
	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User closed query 'If previous question is answered as "YES" the following fields are to be completed. Please verify and enter data.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 00:54:50
Query 'If previous question is answered as "YES" the following fields are to be completed. Please verify and enter data.' answered with 'resolved per query resolution' (Site from CRA).	Abigail Wine (b) (4)	29 Oct 2020 21:30:47
User opened query 'If previous question is answered as "YES" the following fields are to be completed. Please verify and enter data.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:13:19
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
User closed query 'Per CDM: previous response is noted however start and end date are not recorded as there are records for Days 6-11 and Day 13 where O2 Saturation is </=93% or clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 14:09:57
	(b) (4), (b) (6)	10 Nov 2020 03:23:47
Query 'Per CDM: previous response is noted however start and end date are not recorded as there are records for Days 6-11 and Day 13 where O2 Saturation is </=93% or clarify.' answered with 'Updated' (Site from DM).	Jennifer Molstead (b) (4)	09 Nov 2020 23:05:42
	(b) (4)	
User opened query 'Per CDM: previous response is noted however start and end date are not recorded as there are records for Days 6-11 and Day 13 where O2 Saturation is </=93% or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:54:48
User closed query 'Please verify as symptom log notes O2 </= 93% from 05Oct2020 - 12Oct2020' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 00:19:28
Query 'Please verify as symptom log notes O2 </= 93% from 05Oct2020 - 12Oct2020' answered with 'data updated' (Site from CRA).	Tammy Kohn (b) (4)	03 Nov 2020 13:00:18
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	03 Nov 2020 13:00:10
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Tammy Kohn (b) (4)	03 Nov 2020 13:00:10
	(b) (4)	
User opened query 'Please verify as symptom log notes O2 </= 93% from 05Oct2020 - 12Oct2020' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 02:26:13
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered 'No (N)' reason for change: Per Query Resolution	Abigail Wine (b) (4)	29 Oct 2020 21:31:02
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:01:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 18:01:11
User entered 'Yes (Y)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Oct 2020 18:01:11
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:31:05
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:23:12
User entered '05 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	09 Nov 2020 23:05:34
User closed query 'Please verify as symptom log and previous field indicate start date, end date and oxygen saturation fields are to be completed.' (Site from CRA).	(b) (4)	
Query 'Please verify as symptom log and previous field indicate start date, end date and oxygen saturation fields are to be completed.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 04:45:12
DataPoint Un-verified.	Jennifer Molstead (b) (4)	04 Nov 2020 00:25:43
User entered '06 Oct 2020' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Please verify as symptom log and previous field indicate start date, end date and oxygen saturation fields are to be completed.' (Site from CRA).	Jennifer Molstead (b) (4)	04 Nov 2020 00:24:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User closed query 'If previous question is answered as "YES" the following fields are to be completed. Please verify and enter data.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 00:54:48
Query 'If previous question is answered as "YES" the following fields are to be completed. Please verify and enter data.' answered with 'resolved per query resolution' (Site from CRA).	Abigail Wine (b) (4)	29 Oct 2020 21:31:13
User opened query 'If previous question is answered as "YES" the following fields are to be completed. Please verify and enter data.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 20:13:25
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:23:14
User entered '13 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	09 Nov 2020 23:05:34
DataPoint Un-verified.	Jennifer Molstead (b) (4)	04 Nov 2020 00:24:51
User entered '11 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	04 Nov 2020 00:24:51
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:23:23
DataPoint Un-verified.	Jennifer Molstead (b) (4)	04 Nov 2020 00:25:35
User entered '83' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	04 Nov 2020 00:25:35
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:01:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 18:01:11
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Oct 2020 18:01:11
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:31:05
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:01:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 18:01:11
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Oct 2020 18:01:11
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:31:05
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:01:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 18:01:11
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Oct 2020 18:01:11
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:31:05
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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Generated On: 26 Nov 2020 09:22:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Generated On: 26 Nov 2020 09:22:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

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Generated On: 26 Nov 2020 09:22:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Form: Covid-19 Severity Assessment

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05
	(b) (4)	

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Folder: Covid-19 Assessment 30 Sep 2020

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Generated On: 26 Nov 2020 09:22:31

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 18:01:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 18:01:11
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	16 Oct 2020 18:01:11
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:31:05
User entered empty.	Traci Hull (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 09:22:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:31:42
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:05

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:22:31

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:32:22
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Oct 2020 13:31:33

US3402029

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:22:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

US3402029

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:22:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:22:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered '02 Oct 2020'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:22:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:22:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:22:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered '04 Oct 2020'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:22:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:22:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:22:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered '06 Oct 2020'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

US3402029

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:22:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:22:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:22:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered '08 Oct 2020'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:22:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:22:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 00:58:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 00:58:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	21 Oct 2020 00:58:29
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 20:23:57
User entered empty.	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:22:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered '13 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	21 Oct 2020 00:58:29
User entered empty.	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57

US3402029

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:22:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:22:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:29:57
User closed query 'Per source, there is no record of saliva sample collection. Please review and update source or update EDC entries.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:25:43
Query 'Per source, there is no record of saliva sample collection. Please review and update source or update EDC entries.' answered with 'Source updated' (Site from CRA).	Jennifer Molstead (b) (4)	02 Nov 2020 20:35:55
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:17
User opened query 'Per source, there is no record of saliva sample collection. Please review and update source or update EDC entries.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:45:13
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 00:58:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 00:58:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	21 Oct 2020 00:58:29
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 20:23:57
User entered empty.	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:22:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:29:59
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:20
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered '20 Oct 2020' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	21 Oct 2020 00:58:29
User entered empty.	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:22:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:22:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:29:34
User closed query 'Per source, there is no record of saliva sample collection. Please review and update source or update EDC entries.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:25:46
Query 'Per source, there is no record of saliva sample collection. Please review and update source or update EDC entries.' answered with 'Source updated' (Site from CRA).	Jennifer Molstead (b) (4)	02 Nov 2020 20:36:21
User opened query 'Per source, there is no record of saliva sample collection. Please review and update source or update EDC entries.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:45:36
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:27
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	30 Oct 2020 00:05:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 09:56:42
Query 'Data is required. Please complete.' answered with 'will update' (Site from System).	Jennifer Molstead (b) (4)	21 Oct 2020 00:58:38
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 20:23:57
User entered empty.	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:22:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:29:36
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:45:29
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:40:55
User entered '27 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	30 Oct 2020 00:05:13
User entered empty.	Jennifer Molstead (b) (4)	09 Oct 2020 20:23:57

US3402029

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:30
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:22:34

US3402029

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:30
User entered '30 Sep 2020'	Jennifer Molstead (b) (4)	09 Oct 2020 20:22:34
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:30
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:22:34

US3402029

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	09 Oct 2020 20:22:34

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered '30 Sep 2020'	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered '12:05'	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:05'	System	09 Oct 2020 21:02:31

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
DataPoint set to visible.	(b) (4) System	09 Oct 2020 20:22:34

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered missing code ND - Not Done.	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
DataPoint set to visible.	(b) (4) System	09 Oct 2020 20:22:34

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Oct 2020 21:02:44
User entered '98.1' F reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Oct 2020 21:02:31
User entered '98.1' (non-conformant).	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered 'Oral (Oral)'	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered empty.	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered '102'	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 21:02:31

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered '16'	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Oct 2020 21:02:31

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered '121'	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 21:02:31

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:34:47
User entered '92'	Jennifer Molstead (b) (4)	09 Oct 2020 21:02:31
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 21:02:31

US3402029

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:35:15
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	21 Oct 2020 10:56:32

US3402029

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:35:15
User entered '30 Sep 2020'	Jennifer Molstead (b) (4)	21 Oct 2020 10:56:32
	(b) (4)	

US3402029

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:22:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:35:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	09 Oct 2020 20:22:50

US3402029

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 09:22:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:35:29
User entered '30 Sep 2020'	Jennifer Molstead (b) (4)	09 Oct 2020 20:22:50
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:16
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	30 Oct 2020 00:02:51

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:16
User entered '27 Oct 2020'	Jennifer Molstead (b) (4)	30 Oct 2020 00:02:51
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:16
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	30 Oct 2020 00:02:51

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:22:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	30 Oct 2020 00:02:51

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered '27 Oct 2020'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered '07:45'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '27 Oct 2020 07:45'	System	30 Oct 2020 00:04:35

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered '165.5' cm	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
DataPoint set to visible.	(b) (4) System	30 Oct 2020 00:02:51

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered '153.1' kg	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
DataPoint set to visible.	(b) (4) System	30 Oct 2020 00:02:51

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered '36.8' C	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered 'Oral (Oral)'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered empty.	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered '88'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Oct 2020 00:04:35

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered '14'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Oct 2020 00:04:35

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered '141'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 00:04:35

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:36:42
User entered '87'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:35

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:22:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Oct 2020 00:04:35

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:37:04
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:43

US3402029

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:37:04
User entered '27 Oct 2020'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:43
	(b) (4)	

US3402029

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:22:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:37:14
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:55

US3402029

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 09:22:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:37:14
User entered '27 Oct 2020'	Jennifer Molstead (b) (4)	30 Oct 2020 00:04:55
	(b) (4)	

US3402029

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:22:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:57
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4)	03 Oct 2020 19:06:24
User entered 'No (N)'	Traci Hull (b) (4)	28 Jul 2020 14:47:59

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:14
User entered 'USA-US059-2020-mRNA-1273-P301000005'	System	04 Oct 2020 18:34:11
User entered 'New'	(b) (4), (b) (6)	04 Oct 2020 18:34:11

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:04
User closed query 'PV Query: As this event is a confirmed diagnosis of Symptomatic Covid-19, please update term to 'Covid-19'.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:32:35
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)	09 Oct 2020 21:05:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:05:46
Query 'PV Query: As this event is a confirmed diagnosis of Symptomatic Covid-19, please update term to 'Covid-19'.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	09 Oct 2020 20:58:44
Data point term sent to Coder	System	09 Oct 2020 20:58:39
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	09 Oct 2020 20:58:36
Coding entries removed.	Jennifer Molstead (b) (4) (b) (4)	09 Oct 2020 20:58:36
User entered 'COVID-19' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	09 Oct 2020 20:58:36
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User opened query 'PV Query: As this event is a confirmed diagnosis of Symptomatic Covid-19, please update term to 'Covid-19'.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 16:54:20
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: SARS-CoV-2 test positive - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 04:26:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 04:26:38
Data point term sent to Coder	System	03 Oct 2020 19:08:21
User entered 'Positive Sars2 Covid-19'	Jennifer Molstead (b) (4) (b) (4)	03 Oct 2020 19:08:16

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered 'No (N)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 19:08:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 19:08:44
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:44
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 19:08:16
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '29 Sep 2020'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	03 Oct 2020 19:09:56
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4)	03 Oct 2020 19:09:56
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	03 Oct 2020 19:08:16
User entered '12:45'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 19:09:56
User entered '29 Sep 2020 12:45'	System	03 Oct 2020 19:08:16

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:04
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 12:06:10
DataPoint Un-verified.	Jennifer Molstead (b) (4)	28 Oct 2020 12:06:10
User entered 'No (N)' reason for change: New Information	Jennifer Molstead (b) (4)	28 Oct 2020 12:06:10
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 12:05:50
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:04
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 12:32:49
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	28 Oct 2020 12:06:17
DataPoint Un-verified.	Jennifer Molstead (b) (4)	28 Oct 2020 12:05:50
User entered '12 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4)	28 Oct 2020 12:05:50
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:53:08
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:38:03
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'NOT RECOVERED/NOT RESOLVED. NO END DATE REQUIRED.' (Site from Safety).	Traci Hull (b) (4)	16 Oct 2020 17:57:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 12:16:17
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:32:40
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject still hospitalized' (Site from Safety).	Jennifer Molstead (b) (4)	09 Oct 2020 20:58:56
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40

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If not Ongoing, end date (dd MMM yyyy)

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)	08 Oct 2020 16:55:54
	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

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Folder: Adverse Events

Form: Adverse Events (1)

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Oct 2020 19:08:16

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:04
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 12:40:16
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	28 Oct 2020 13:44:40
DataPoint Un-verified.	Jennifer Molstead (b) (4)	28 Oct 2020 13:44:20
User entered 'Grade 4 (Grade 4)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	28 Oct 2020 13:44:20
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:53:33
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '0'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '0'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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)	12 Oct 2020 12:39:03
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
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 'correct as is' (Site from System).	Jennifer Molstead (b) (4)	07 Oct 2020 20:30:22
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	07 Oct 2020 20:29:58
User entered '1' reason for change: New Information	Jennifer Molstead (b) (4)	07 Oct 2020 20:29:58
User entered '0'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Per source document hospital admission date was 07 Oct 2020. Yet, treatment medications were initiated prior to 07 Oct 2020. Please review dates and reconcile accordingly, or confirm.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:22:29
User opened query 'PV Query: Per source document hospital admission date was 07 Oct 2020. Yet, treatment medications were initiated prior to 07 Oct 2020. Please review dates and reconcile accordingly, or confirm.' (Site from Safety).	(b) (4), (b) (6)	13 Oct 2020 12:17:13
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '07 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4)	07 Oct 2020 20:29:58
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:04
DataPoint Un-verified.	Jennifer Molstead (b) (4)	18 Oct 2020 14:07:42
User entered '13 Oct 2020' reason for change: New Information	(b) (4)	
	Jennifer Molstead (b) (4)	18 Oct 2020 14:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:04
DataPoint Un-verified.	Jennifer Molstead (b) (4)	18 Oct 2020 14:07:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Jennifer Molstead (b) (4)	18 Oct 2020 14:07:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '0'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '0'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '1'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:04
User closed query 'PV Query: As the last dose of study drug was given on 24 Aug 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:32:48
Query 'PV Query: As the last dose of study drug was given on 24 Aug 2020, please update the action taken with study drug from none to not applicable.' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	09 Oct 2020 20:59:23
DataPoint Un-verified.	Jennifer Molstead (b) (4)	09 Oct 2020 20:59:16
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	09 Oct 2020 20:59:16
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User opened query 'PV Query: As the last dose of study drug was given on 24 Aug 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 16:56:12
User entered 'None (NONE)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '0'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '1'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered '0'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:04
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until it is achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 12:40:31
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 it is achieved.' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	28 Oct 2020 12:06:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jennifer Molstead (b) (4)	28 Oct 2020 12:05:50
Data Entry Error		
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 it is achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:51:59
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 16:38:08
DataPoint Un-verified.	Jennifer Molstead (b) (4)	18 Oct 2020 14:07:42
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Jennifer Molstead (b) (4)	18 Oct 2020 14:07:42
Data Entry Error		
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'CORRECT AS IS' (Site from Safety).	Traci Hull (b) (4)	16 Oct 2020 17:56:32
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)	13 Oct 2020 12:14:50

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:32:55
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject is still hospitalized' (Site from Safety).	Jennifer Molstead (b) (4)	09 Oct 2020 20:59:37
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 16:55:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:04
User closed query 'Per DM CLR: SAE Narrative indicates Oxygen and Plasma were given. However, there is no corresponding ConMed record to match these information. Please update to record the medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:33:24
Query 'Per DM CLR: SAE Narrative indicates Oxygen and Plasma were given. However, there is no corresponding ConMed record to match these information. Please update to record the medications as appropriate. Otherwise, clarify.' answered with 'Oxygen was added. Convalescent plasma was already documented' (Site from DM).	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:54
User closed 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)	29 Oct 2020 12:40:36
User opened query 'Per DM CLR: SAE Narrative indicates Oxygen and Plasma were given. However, there is no corresponding ConMed record to match these information. Please update to record the medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 13:57:20
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.' answered with 'Faxed' (Site from Safety).	Jennifer Molstead (b) (4)	28 Oct 2020 12:06:37
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)	23 Oct 2020 16:55:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS EXPOSED AT PLACE OF EMPLOYMENT. SUBJECT BECAME SYMPTOMATIC. SUBJECT WAS DOING BETTER AS OF 06OCT2020 WHEN SPOKEN TO FOR NIGHTLY CONVALESCENT CALL. SITE WAS NOTIFIED BY A FRIEND THAT THE SUBJECTS O2 SATURATION WAS DECLINING AND THAT THE SUBJECT WAS HAVING DIFFICULTY BREATHING. SHE THEN WENT TO THE EMERGENCY ROOM WHERE SHE WAS LATER ADMITTED TO THE COVID UNIT OF THE HOSPITAL. SUBJECT HAS BEEN STARTED ON OXYGEN, RAMDESAVIRE AND CONVALESCENT PLASMA. SUBJECT ALSO HAD CHEST XRAY UPON ADMISSION WHICH SHOWED BIBASILAR INFILTRATE.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	18 Oct 2020 14:07:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 16:11:56
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)	13 Oct 2020 12:19:21
User closed 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)	12 Oct 2020 14:33:03
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 14:33:00
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'No tests available at this time' (Site from Safety).	Jennifer Molstead (b) (4)	09 Oct 2020 21:01:14

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Con Med Log has been updated' (Site from Safety). DataPoint Un-verified.	Jennifer Molstead (b) (4)	(b) (4) 09 Oct 2020 21:01:02
User entered 'SUBJECT WAS EXPOSED AT PLACE OF EMPLOYMENT. SUBJECT BECAME SYMPTOMATIC.	Jennifer Molstead (b) (4)	(b) (4) 09 Oct 2020 21:00:49
SUBJECT WAS DOING BETTER AS OF 06OCT2020 WHEN SPOKEN TO FOR NIGHTLY CONVALESCENT CALL. SITE WAS NOTIFIED BY A FRIEND THAT THE SUBJECTS O2 SATURATION WAS DECLINING AND THAT THE SUBJECT WAS HAVING DIFFICULTY BREATHING. SHE THEN WENT TO THE EMERGENCY ROOM WHERE SHE WAS LATER ADMITTED TO THE COVID UNIT OF THE HOSPITAL. SUBJECT HAS BEEN STARTED ON OXYGEN, RAMDESAVIRE AND CONVALESCENT PLASMA.' reason for change: Per Query Resolution DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:44:40
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)	08 Oct 2020 16:55:36
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)	08 Oct 2020 16:55:17

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS EXPOSED AT PLACE OF EMPLOYMENT. SUBJECT BECAME SYMPTOMATIC. Subject was doing better as of 06Oct2020 when spoken to for nightly convalescent call. Site was notified by a friend that the subjects O2 saturation was declining and that the subject was having difficulty breathing. She then went to the Emergency Room where she was later admitted to the Covid Unit of the hospital. Subject has been started on oxygen, Ramdesavire and convalescent plasma. Dosages, Liters and Units are unknown at this time. will update con med log as soon as information is available.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Oct 2020 20:29:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Oct 2020 19:09:56
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Oct 2020 19:09:56
User entered 'Subject was exposed at place of employment. Subject became symptomatic' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	03 Oct 2020 19:09:56
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Oct 2020 19:08:16
User entered empty.	Jennifer Molstead (b) (4)	03 Oct 2020 19:08:16

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 19:08:16

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Oct 2020 19:08:16

US3402029

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
User entered '0'	System	18 Oct 2020 14:07:42

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:22:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:46:38
User closed query 'Per ETRTR: AE CRF for COVID 19 indicates medication is dosed. Please add Medication details as expected, thanks.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 00:57:04
Query 'Per ETRTR: AE CRF for COVID 19 indicates medication is dosed. Please add Medication details as expected, thanks.' answered with 'CORRECT AS IS' (Site from CRA).	Traci Hull (b) (4)	16 Oct 2020 17:57:58
User opened query 'Per ETRTR: AE CRF for COVID 19 indicates medication is dosed. Please add Medication details as expected, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 16:25:26
User entered 'Yes (Y)'	Traci Hull (b) (4)	28 Jul 2020 14:48:15

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jul 2020 14:51:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jul 2020 14:51:14
Data point term sent to Coder	System	28 Jul 2020 14:50:17
User entered 'levothyroxine'	Traci Hull (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'hypothyroidism'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '137'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User closed query 'Per DM CLR: Please review Dose unit "Other" specified as "MICROGRAMS" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 09:12:53
Query 'Per DM CLR: Please review Dose unit "Other" specified as "MICROGRAMS" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'UPDATED' (Site from DM).	Tarin Gordon (b) (4) (b) (4)	03 Oct 2020 14:24:04
User entered 'ug (ug)' reason for change: Data Entry Error	Tarin Gordon (b) (4) (b) (4)	03 Oct 2020 14:23:57
User opened query 'Per DM CLR: Please review Dose unit "Other" specified as "MICROGRAMS" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 09:14:50
User entered 'Other (OTHER)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty; reason for change Data Entry Error	Tarin Gordon (b) (4)	03 Oct 2020 14:23:57
User entered 'micrograms'	Traci Hull (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	28 Jul 2020 14:49:52
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
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)	03 Aug 2020 17:45:00
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)	28 Jul 2020 14:50:42
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	28 Jul 2020 14:49:52
User entered 'un Jul 2004'	Traci Hull (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Jul 2020 14:49:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jul 2020 14:52:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jul 2020 14:52:18
Data point term sent to Coder	System	28 Jul 2020 14:51:17
User entered 'lexapro'	Traci Hull (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'anxiety'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '20'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	28 Jul 2020 14:50:28
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
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)	03 Aug 2020 17:45:06
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)	28 Jul 2020 14:50:35
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	28 Jul 2020 14:50:28
User entered 'un Feb 2016'	Traci Hull (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '0'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Jul 2020 14:50:28

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:10:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:10:12
Data point term sent to Coder	System	07 Oct 2020 13:28:48
User entered 'MUCINEX'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'COVID'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '600'	Traci Hull (b) (4)	07 Oct 2020 13:27:52
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:27:52
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	07 Oct 2020 13:27:52
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '3 Oct 2020'	Traci Hull (b) (4)	07 Oct 2020 13:27:52
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:27:52
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:36
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:41:29
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Updated' (Site from DM).	Jennifer Molstead (b) (4)	06 Nov 2020 20:55:51
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 20:55:40
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	06 Nov 2020 20:55:40
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:06:25
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 02:32:38
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 20:55:40
User entered '06 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4)	06 Nov 2020 20:55:40
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 13:27:52

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
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)	07 Oct 2020 15:21:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:21:00
Data point term sent to Coder	System	07 Oct 2020 13:28:48
User entered 'dexamethasone'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Traci Hull (b) (4)	07 Oct 2020 13:28:46
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'COVID'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:10:02
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 20:57:11
User entered '6' reason for change: New Information	Jennifer Molstead (b) (4)	06 Nov 2020 20:57:11
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '4'	Traci Hull (b) (4)	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:28:46
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:28:46
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	07 Oct 2020 13:28:46
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '5 Oct 2020'	Traci Hull (b) (4)	07 Oct 2020 13:28:46
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '0'	Traci Hull (b) (4)	07 Oct 2020 13:28:46
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:37:51
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:41:39
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Updated' (Site from DM).	Jennifer Molstead (b) (4)	06 Nov 2020 20:56:44
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 20:56:39
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	06 Nov 2020 20:56:39
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:07:37
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Yes (Y)'	Traci Hull (b) (4)	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Please update ConMed page' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 04:10:09
User opened query 'Please update ConMed page' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:38:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:37:53
User entered '17 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4)	06 Nov 2020 20:58:57
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 20:56:39
User entered '12 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4)	06 Nov 2020 20:56:39
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Traci Hull (b) (4)	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 13:28:46

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 00:00:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	08 Oct 2020 00:00:21
Data point term sent to Coder	System	07 Oct 2020 20:46:02
User entered 'Doxycycline'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Covid'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '100'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '07 Oct 2020'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '0'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:51:35
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:41:53
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 21:02:20
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	06 Nov 2020 21:02:20
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'UPdated' (Site from DM).	Jennifer Molstead (b) (4)	06 Nov 2020 21:01:38
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:08:11
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Please enter end date on source.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 04:09:30
User opened query 'Please enter end date on source.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:52:00
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:51:38
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Nov 2020 21:02:20
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Nov 2020 21:01:32
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 21:01:32
User entered '17 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4)	06 Nov 2020 21:01:32
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:45:26

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Oct 2020 20:45:26

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 20:45:26

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 20:45:26

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
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)	23 Nov 2020 07:25:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:25:14
Data point term sent to Coder	System	06 Nov 2020 21:08:52
Coding entries removed.	Jennifer Molstead (b) (4) (b) (4)	06 Nov 2020 21:07:59
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
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)	07 Oct 2020 22:02:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 22:02:26
Data point term sent to Coder	System	07 Oct 2020 20:47:03
User entered 'Remdesivir'	Jennifer Molstead (b) (4) (b) (4)	07 Oct 2020 20:46:41

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Covid'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '200'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:52:47
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 21:07:59
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	06 Nov 2020 21:07:59
reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '07 Oct 2020'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '0'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:52:55
User entered '07 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4)	06 Nov 2020 21:03:20
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 21:02:58
User entered '12 Oct 2020' reason for change: New Information	Jennifer Molstead (b) (4)	06 Nov 2020 21:02:58
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '07 Oct 2020'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:46:41

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 20:46:41

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 20:46:41

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 20:46:41

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: OTHER BLOOD PRODUCTS, PRODUCT: PLASMA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 09:30:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 09:30:32
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
Data point term sent to Coder	System	07 Oct 2020 20:49:07
User entered 'Convalescent Plasma'	Jennifer Molstead (b) (4) (b) (4)	07 Oct 2020 20:49:06

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Covid'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '1'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Units'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '07 Oct 2020'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered '0'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:53:56
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:42:06
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'UPDATED' (Site from DM).	Jennifer Molstead (b) (4)	07 Nov 2020 15:47:08
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Nov 2020 15:47:00
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 15:47:00
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:05:41
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Please enter end date on ConMed log.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 04:08:40
User opened query 'Please enter end date on ConMed log.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 04:00:24
Query 'Please enter end date on source.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 04:00:00
User opened query 'Please enter end date on source.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:54:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:53:57
DataPoint Un-verified.	Jennifer Molstead (b) (4)	07 Nov 2020 15:47:00
User entered '08 Oct 2020' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	07 Nov 2020 15:47:00
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered empty.	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:42:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	07 Oct 2020 20:49:06
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 20:49:06

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 20:49:06

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 20:49:06

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'The oxygen therapy is not in source. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:14:33
Query 'The oxygen therapy is not in source. Please review and update entries.' answered with 'DATA UPDATED' (Site from CRA).	Tammy Kohn (b) (4)	02 Nov 2020 19:14:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User opened query 'The oxygen therapy is not in source. Please review and update entries.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 19:53:43
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)	30 Oct 2020 05:29:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 05:29:51
Data point term sent to Coder	System	29 Oct 2020 22:57:09
User entered 'Oxygen'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'Covid-19'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 03:55:55
User closed query 'Per CDM: Per eCRF completion guidelines pg. 36, unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 18:42:19
Query 'Per CDM: Per eCRF completion guidelines pg. 36, unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	06 Nov 2020 21:24:58
DataPoint Un-verified.	Jennifer Molstead (b) (4)	06 Nov 2020 21:24:52
User entered '4' reason for change: New Information	Jennifer Molstead (b) (4)	06 Nov 2020 21:24:52
User opened query 'Per CDM: Per eCRF completion guidelines pg. 36, unknown dose should be recorded as UNK. Please update UNKNOWN to UNK, otherwise provide dose if known.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:35:22
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'Unknown'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'liters'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'Continuous'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'Nasal (NASAL)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered empty.	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered '07 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered '0'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered '11 Oct 2020'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:53:45
User entered 'No (N)'	Jennifer Molstead (b) (4)	29 Oct 2020 22:57:07

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:57:07

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:57:07

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:57:07

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per source reviewed, Acetaminophen was not recorded. Please review and update source or AE eCRF.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:14:46
Query 'Per source reviewed, Acetaminophen was not recorded. Please review and update source or AE eCRF.' answered with 'please check page 2 of the of the medication log' (Site from CRA).	Jennifer Molstead (b) (4)	06 Nov 2020 21:12:12
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User opened query 'Per source reviewed, Acetaminophen was not recorded. Please review and update source or AE eCRF.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 01:09:04
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)	04 Nov 2020 22:27:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:27:36
Data point term sent to Coder	System	04 Nov 2020 22:26:52
User entered 'acetaminophen'	Abigail Wine (b) (4)	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'No (N)'	Abigail Wine (b) (4)	04 Nov 2020 22:26:31
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'COVID'	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered '1300'	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered empty.	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'as needed (PRN)'	Abigail Wine (b) (4)	04 Nov 2020 22:26:31
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered empty.	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'Oral (ORAL)'	Abigail Wine (b) (4)	04 Nov 2020 22:26:31
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered empty.	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered '1 Oct 2020'	Abigail Wine (b) (4)	04 Nov 2020 22:26:31
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered '0'	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'No (N)'	Abigail Wine (b) (4)	04 Nov 2020 22:26:31
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered '1 Oct 2020'	Abigail Wine (b) (4)	04 Nov 2020 22:26:31
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'No (N)'	Abigail Wine (b) (4)	04 Nov 2020 22:26:31
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:26:31

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:45:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:45:54
User closed query 'Per source reviewed, Excedrin was not recorded. Please review and update source or AE eCRF.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 03:14:51
Query 'Per source reviewed, Excedrin was not recorded. Please review and update source or AE eCRF.' answered with 'This is located on page 2 of the medication log' (Site from CRA).	Jennifer Molstead (b) (4) (b) (4)	06 Nov 2020 21:11:13
User opened query 'Per source reviewed, Excedrin was not recorded. Please review and update source or AE eCRF.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 01:09:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:22:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:22:35
Data point term sent to Coder	System	04 Nov 2020 22:27:54
User entered 'EXCEDRIN'	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'No (N)'	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'COVID'	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered '650'	Abigail Wine (b) (4)	04 Nov 2020 22:27:09
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'mg (mg)'	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered empty.	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'as needed (PRN)'	Abigail Wine (b) (4)	04 Nov 2020 22:27:09
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered empty.	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'Oral (ORAL)'	Abigail Wine (b) (4)	04 Nov 2020 22:27:09
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered empty.	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered '1 Oct 2020'	Abigail Wine (b) (4)	04 Nov 2020 22:27:09
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered '0'	Abigail Wine (b) (4) (b) (4)	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'No (N)'	Abigail Wine (b) (4)	04 Nov 2020 22:27:09
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered '1 Oct 2020'	Abigail Wine (b) (4)	04 Nov 2020 22:27:09
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 01:09:09
User entered 'No (N)'	Abigail Wine (b) (4)	04 Nov 2020 22:27:09
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 22:27:09

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:06:58
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)	07 Nov 2020 07:08:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:08:27
Data point term sent to Coder	System	06 Nov 2020 21:08:52
Data point term sent to Coder	System	06 Nov 2020 21:05:50
User entered 'Remdesivir'	Jennifer Molstead (b) (4) (b) (4)	06 Nov 2020 21:05:32

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:00
User entered 'No (N)'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:02
User entered 'Sars Covid 19'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:03
User entered '100'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:05
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:07
User entered empty.	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:09
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:10
User entered empty.	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:12
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	06 Nov 2020 21:08:36
reason for change: New Information	(b) (4)	
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:14
User entered empty.	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:15
User entered '08 Oct 2020'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:22
User entered '0'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:24
User entered 'No (N)'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:26
User entered '12 Oct 2020'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32
	(b) (4)	

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 04:07:28
User entered 'No (N)'	Jennifer Molstead (b) (4)	06 Nov 2020 21:05:32

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 21:05:32

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 21:05:32

US3402029

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:22:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 21:05:32

US3402029

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:22:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:54:08
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	18 Oct 2020 14:07:53
User entered 'No (N)'	Traci Hull (b) (4)	28 Jul 2020 14:51:02

US3402029

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:22:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:55:33
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:54:25
User entered '07 Oct 2020'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:08:44

US3402029

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:22:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Query 'Please update source with Chest X-Ray.'	Jennifer Molstead (b) (4)	02 Nov 2020 20:33:58
answered with 'UPdated' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:55:35
User opened query 'Please update source with Chest	(b) (4), (b) (6)	30 Oct 2020 19:55:32
X-Ray.' (Site from CRA).		
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:54:25
User entered 'CHEST X-RAY'	Jennifer Molstead (b) (4)	18 Oct 2020 14:08:44
	(b) (4)	

US3402029

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:22:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:55:37
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:54:25
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:08:44

US3402029

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:22:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 19:55:38
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:54:25
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Oct 2020 14:08:44

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'USA-US059-2020-MRNA-1273-P301000005'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
Un-reviewed for Safety.	System	07 Oct 2020 20:29:58
User entered 'Yes (Y)'	System	07 Oct 2020 20:29:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Frank'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Eder'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '1290 Upper Front Street'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Binghamton'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'NY'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '13901'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
User entered 'US'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Oct 2020 12:33:18
User entered '4'	System	20 Oct 2020 17:27:27
User entered '3'	System	12 Oct 2020 14:38:30
User entered '2'	System	08 Oct 2020 12:45:17
User entered '1'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'USA-US059-2020-MRNA-1273-P301000005'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
Un-reviewed for Safety.	System	07 Oct 2020 20:29:58
User entered 'Yes (Y)'	System	07 Oct 2020 20:29:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Frank'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Eder'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '1290 Upper Front Street'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Binghamton'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'NY'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '13901'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
User entered 'US'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Oct 2020 12:33:18
User entered '4'	System	20 Oct 2020 17:27:27
User entered '3'	System	12 Oct 2020 14:38:30
User entered '2'	System	08 Oct 2020 12:45:17
User entered '1'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
User entered '04/Oct/2020 14:34'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:22:31

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)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
User entered '1'	(b) (4), (b) (6)	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'USA-US059-2020-MRNA-1273-P301000005'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
Un-reviewed for Safety.	System	07 Oct 2020 20:29:58
User entered 'Yes (Y)'	System	07 Oct 2020 20:29:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Frank'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Eder'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '1290 Upper Front Street'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Binghamton'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'NY'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '13901'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
User entered 'US'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Oct 2020 12:33:18
User entered '4'	System	20 Oct 2020 17:27:27
User entered '3'	System	12 Oct 2020 14:38:30
User entered '2'	System	08 Oct 2020 12:45:17
User entered '1'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
User entered '08/Oct/2020 12:45'	System	08 Oct 2020 12:45:17

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:22:31

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)
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:38:18
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
User entered '1'	(b) (4), (b) (6)	08 Oct 2020 12:45:17

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'USA-US059-2020-MRNA-1273-P301000005'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
Un-reviewed for Safety.	System	07 Oct 2020 20:29:58
User entered 'Yes (Y)'	System	07 Oct 2020 20:29:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Frank'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Eder'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '1290 Upper Front Street'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Binghamton'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'NY'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '13901'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
User entered 'US'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Oct 2020 12:33:18
User entered '4'	System	20 Oct 2020 17:27:27
User entered '3'	System	12 Oct 2020 14:38:30
User entered '2'	System	08 Oct 2020 12:45:17
User entered '1'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:49:55
User entered '12/Oct/2020 14:38'	System	12 Oct 2020 14:38:30

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:22:31

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)	30 Oct 2020 19:49:55
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 17:27:16
User entered '1'	(b) (4), (b) (6)	12 Oct 2020 14:38:30

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'USA-US059-2020-MRNA-1273-P301000005'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
Un-reviewed for Safety.	System	07 Oct 2020 20:29:58
User entered 'Yes (Y)'	System	07 Oct 2020 20:29:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Frank'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Eder'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '1290 Upper Front Street'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Binghamton'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'NY'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '13901'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
User entered 'US'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Oct 2020 12:33:18
User entered '4'	System	20 Oct 2020 17:27:27
User entered '3'	System	12 Oct 2020 14:38:30
User entered '2'	System	08 Oct 2020 12:45:17
User entered '1'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:49:55
User entered '20/Oct/2020 17:27'	System	20 Oct 2020 17:27:27

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:22:31

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)	30 Oct 2020 19:49:55
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 12:33:08
User entered '1'	(b) (4), (b) (6)	20 Oct 2020 17:27:27

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'USA-US059-2020-MRNA-1273-P301000005'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
Un-reviewed for Safety.	System	07 Oct 2020 20:29:58
User entered 'Yes (Y)'	System	07 Oct 2020 20:29:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'No (N)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Yes (Y)'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Frank'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Eder'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '1290 Upper Front Street'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'Binghamton'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered 'NY'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Oct 2020 18:34:29
User entered '13901'	System	04 Oct 2020 18:34:11

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 19:43:44
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:44:51
User entered 'US'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:22:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	29 Oct 2020 12:33:18
User entered '4'	System	20 Oct 2020 17:27:27
User entered '3'	System	12 Oct 2020 14:38:30
User entered '2'	System	08 Oct 2020 12:45:17
User entered '1'	System	04 Oct 2020 18:34:35

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:22:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:49:55
User entered '29/Oct/2020 12:33'	System	29 Oct 2020 12:33:18

US3402029

Folder: SAE USA-US059-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:22:31

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)	30 Oct 2020 19:49:55
User entered '1'	(b) (4), (b) (6)	29 Oct 2020 12:33:18