

US3272026 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:54:31

All time stamps listed in this document are displayed in GMT

US3272026

Form: Participant Creation

Generated On: 26 Nov 2020 10:54:31

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
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 10:54:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	01 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:54:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:54:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

Condition	BILATERAL AXILLARY SKIN TAGS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 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 10:54:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:47 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 08:47
Height (<i>xxx.x</i>)	185.0 cm
Weight (<i>xxx.x</i>)	123.2 kg
BMI (<i>xxx.x</i>)	35.99708 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

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.

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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 False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

What was the date of randomization? (dd MMM yyyy) 01 AUG 2020

What was the participant's randomization number? 100363

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 10:54:31

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 10:54:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 AUG 2020
Time of assessment (00:00-23:59)	08:47 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 08:47
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 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 10:54:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 AUG 2020
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 10:42
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	01 AUG 2020
What was the treatment time? (00:00-23:59)	10:10 (24 HR)
Treatment Date and Time (derived)	01 AUG 2020 10:10
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
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 10:54:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	01 AUG 2020
Collection time (<i>00:00-23:59</i>)	09:26 (24 HR)
Collection date and time (derived)	01 AUG 2020 09:26

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:31

Collection date (<i>dd MMM yyyy</i>)			01 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	09:20	01 AUG 2020 09:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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 10:54:31

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

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

01 AUG 2020 10:50

PC Open Date & Time

01 AUG 2020 10:30

PC Close Date & Time

01 AUG 2020 13:00

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 98.2 °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	02 AUG 2020 01:03
PC Open Date & Time	01 AUG 2020 13:55
PC Close Date & Time	02 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

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

02 AUG 2020 22:06

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 21:07

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 20:41

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 21:26

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

98.1 °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

06 AUG 2020 18:56

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

98.3 °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

07 AUG 2020 17:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 10:50

PC Open Date & Time

01 AUG 2020 10:30

PC Close Date & Time

01 AUG 2020 13:00

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

02 AUG 2020 01:04

PC Open Date & Time

01 AUG 2020 13:55

PC Close Date & Time

02 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

02 AUG 2020 22:07

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

03 AUG 2020 21:08

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

04 AUG 2020 20:41

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

05 AUG 2020 21:26

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

06 AUG 2020 18:56

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

07 AUG 2020 17:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 10:51
PC Open Date & Time	01 AUG 2020 10:30
PC Close Date & Time	01 AUG 2020 13:00

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 01:04
PC Open Date & Time	01 AUG 2020 13:55
PC Close Date & Time	02 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 22:08
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 21:08
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 20:41
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 21:27
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 18:57
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 17:27
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

Was Contact Attempted?

Yes ☒

No ☐

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

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:26
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:05
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3272026

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	08 SEP 2020
What was the treatment time? (00:00-23:59)	11:33 (24 HR)
Treatment Date and Time (derived)	08 SEP 2020 11:33
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	8 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:46 (24 HR)
Collection date and time (derived)	8 SEP 2020 10:46

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:31

Collection date (<i>dd MMM yyyy</i>)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:36	8 SEP 2020 10:36
Nasopharyngeal Swab 2	No		

US3272026

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

08 SEP 2020 12:05

PC Open Date & Time

08 SEP 2020 11:53

PC Close Date & Time

08 SEP 2020 14:23

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 97.5 °F

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

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

PC Time Stamp	08 SEP 2020 20:25
PC Open Date & Time	08 SEP 2020 15:18
PC Close Date & Time	09 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

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

10 SEP 2020 23:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 15:25

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

97.9 °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

12 SEP 2020 12:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

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

13 SEP 2020 12:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

98.1 °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

14 SEP 2020 18:46

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

08 SEP 2020 12:09

PC Open Date & Time

08 SEP 2020 11:53

PC Close Date & Time

08 SEP 2020 14:23

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

08 SEP 2020 20:26

PC Open Date & Time

08 SEP 2020 15:18

PC Close Date & Time

09 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

09 SEP 2020 16:03

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

10 SEP 2020 23:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

11 SEP 2020 15:26

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

12 SEP 2020 12:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

13 SEP 2020 12:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

14 SEP 2020 18:46

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:09
PC Open Date & Time	08 SEP 2020 11:53
PC Close Date & Time	08 SEP 2020 14:23

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 20:27
PC Open Date & Time	08 SEP 2020 15:18
PC Close Date & Time	09 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:03
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 23:41
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 15:26
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:46
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

Was Contact Attempted?

Yes ☒

No ☐

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

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

Was Contact Attempted?

Yes ☒

No ☐

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

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

Was Contact Attempted?

Yes ☒

No ☐

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

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:53 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 12:53
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272026

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	9 OCT 2020
Collection time (<i>00:00-23:59</i>)	13:05 (24 HR)
Collection date and time (derived)	9 OCT 2020 13:05

US3272026

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

01 OCT 2020 06:25:56

Patient Cloud Open Date & Time

01 OCT 2020 00:01

Patient Cloud Close Date & Time

05 OCT 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

08 OCT 2020 07:53:24

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

15 OCT 2020 10:37:14

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

29 OCT 2020 07:11:00

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

05 NOV 2020 09:42:19

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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	12 NOV 2020 11:45:31
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2020 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2020 00:01
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Patient Cloud Close Date & Time	09 OCT 2020 23:59
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US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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	19 NOV 2020 08:40:43
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	21 DEC 2020 00:01
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Patient Cloud Close Date & Time	25 DEC 2020 23:59
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US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUL 2021 00:01
Patient Cloud Close Date & Time	09 JUL 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUL 2021 00:01
Patient Cloud Close Date & Time	16 JUL 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 JUL 2021 00:01
Patient Cloud Close Date & Time	23 JUL 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUL 2021 00:01
Patient Cloud Close Date & Time	30 JUL 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	16 AUG 2021 00:01
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Patient Cloud Close Date & Time	20 AUG 2021 23:59
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US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 SEP 2021 00:01
Patient Cloud Close Date & Time	10 SEP 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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°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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2021 00:01
Patient Cloud Close Date & Time	29 OCT 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 NOV 2021 00:01
Patient Cloud Close Date & Time	19 NOV 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JAN 2022 00:01
Patient Cloud Close Date & Time	07 JAN 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 FEB 2022 00:01
Patient Cloud Close Date & Time	11 FEB 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 FEB 2022 00:01
Patient Cloud Close Date & Time	18 FEB 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 APR 2022 00:01
Patient Cloud Close Date & Time	22 APR 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2022 00:01
Patient Cloud Close Date & Time	17 JUN 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2022 00:01
Patient Cloud Close Date & Time	24 JUN 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2022 00:01
Patient Cloud Close Date & Time	01 JUL 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2022 00:01
Patient Cloud Close Date & Time	08 JUL 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2022 00:01
Patient Cloud Close Date & Time	22 JUL 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2022 00:01
Patient Cloud Close Date & Time	29 JUL 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	15 AUG 2022 00:01
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Patient Cloud Close Date & Time	19 AUG 2022 23:59
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US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2022 00:01
Patient Cloud Close Date & Time	09 SEP 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3272026

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:54:31

Date of Contact	11 NOV 2020
Time of Contact	14:19
Date and Time of Contact (derived)	11 NOV 2020 14:19
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	336 of 2301	

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	340 of 2301	

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
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Form: Symptom Log (3)

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

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Form: Symptom Log (3)

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

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (4)

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	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	348 of 2301	

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Form: Symptom Log (4)

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

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Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	352 of 2301	

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	356 of 2301	

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (7)

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[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	101.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input checked="" type="checkbox"/>
v6.020 DTW (1102)	360 of 2301	

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Form: Symptom Log (7)

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

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Form: Symptom Log (7)

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

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Form: Symptom Log (8)

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
v6.020 DTW (1102)	364 of 2301	

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Form: Symptom Log (8)

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

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Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	80 %	
O2 Saturation Units	%	
Temperature	103.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	368 of 2301	

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	372 of 2301	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	100.2 F	
Chills	None <input type="checkbox"/>	
	Mild <input checked="" type="radio"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Cough	None <input type="checkbox"/>	
	Mild <input type="checkbox"/>	
	Moderate <input checked="" type="radio"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Shortness of Breath	None <input type="checkbox"/>	
	Mild <input type="checkbox"/>	
	Moderate <input checked="" type="radio"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Difficulty Breathing	None <input type="checkbox"/>	
	Mild <input type="checkbox"/>	
	Moderate <input checked="" type="radio"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Fatigue	None <input type="checkbox"/>	
v6.020 DTW (1102)	376 of 2301	

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	380 of 2301	

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Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
v6.020 DTW (1102)	384 of 2301	

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Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	388 of 2301	

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	392 of 2301	

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	68 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
v6.020 DTW (1102)	396 of 2301	

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

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

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Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

Date of Visit	12 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	12 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

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 _____ 16 NOV 2020

End Date _____

Oxygen Saturation _____ 68 %

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 _____ 16 NOV 2020

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

Start Date _____ 16 NOV 2020

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

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☒ No ☐

Start Date 16 NOV 2020

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 16 NOV 2020

Hepatic Dysfunction? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒
No ☐

Date of Assessment 16 NOV 2020

Radiographical Evidence Yes ☒
No ☐

Date of Assessment 16 NOV 2020

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

Start Date 16 NOV 2020

End Date

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:54:31

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 10:54:31

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	13:10 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 13:10
Height (<i>xxx.x</i>)	178 cm
Weight (<i>xxx.x</i>)	122.9 kg
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3272026

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:54:31

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 NOV 2020

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

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.

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Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 10:54:31

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3272026

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Nov 2020 00:48:06

Generated On: 26 Nov 2020 10:54:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	COVID19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	08 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	2

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

PCT CALLED AND REPORTED
O2 SATURATION IN THE 80S%.
DIRECTED PATIENT TO
EMERGENCY DEPARTMENT
FOR SUSTAINED HYPOXIA.
FOUND TO BE 78% ON RA.
PATIENT STARTED ON BIPAP
WITH O2 75% AND
TRANSFERRED TO ICU. DX
WITH ACUTE RESPIRATORY
FAILURE, AKI, ARDS, AND
MULTIFOCAL PNEUMONIA.

WAS STARTED ON ALBUTEROL
SULFATE, DELTASONE,
CEFTRIAXONE,
AZITHROMYCIN,
DEXAMETHASONE,
EXNOXAPARIN, REMDESIVIR
UPON ADMISSION.
REQUESTING FURTHER
INFORMATION.

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)	1

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:54:31

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

Yes ☒

No ☐

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

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	FEXOFENADINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SEASONAL ALLERGIES
Dose per administration	30
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2013
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	ALBUTEROL SULFATE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	WHEEZING
Dose per administration	2.5
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

Name of Medication DELTASONE (CALCIUM
STEARATE, CORN STARCH,
ERYTHROSINE SODIUM,
LACTOSE, MINERAL OIL,
SORBIC ACID AND SUCROSE.)

Prophylaxis Yes ☐
No ☒

Indication RESPIRATORY FAILURE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	DEXAMETHASONE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	ACUTE HYPOXIC RESPIRATORY FAILURE
Dose per administration	20
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	PIPERACILLIN-TAZOBACTAM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	BILATERAL PNEUMONIA
Dose per administration	3.375
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	AZITHROMYCIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BILATERAL PNEUMONIA
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	CEFTRIAXONE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	BILATERAL PNEUMONIA
Dose per administration	2
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input checked="" type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	16 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	ENOXAPARIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DVT PROPHYLAXIS
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	REMDESIVIR
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	COVID 19
Dose per administration	100
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	16 NOV 2020
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:54:31

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:54:31

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
16 NOV 2020	CHEST X RAY	Adverse Event	
16 NOV 2020	CAT SCAN	Adverse Event	
17 NOV 2020	CHEST X RAY	Adverse Event	

US3272026

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:54:31

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

US3272026

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:54:31

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/NOV/2020 14:11
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

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:54:31

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	18/NOV/2020 10:47
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.	<input checked="" type="checkbox"/> True

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:54:31

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/NOV/2020 15:02
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

US3272026 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272026

Form: Participant Creation

Generated On: 26 Nov 2020 10:54:31

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3272026'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	01 Aug 2020 14:39:10

US3272026

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:19
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:16:46

US3272026

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	10 Sep 2020 15:45:09
User entered '01 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:45:09
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:16:09
User entered '28 Jul 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:16:09
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:15:11
User entered '01 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:15:11
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:14:38
User closed query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 22:14:38
Query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	09 Sep 2020 22:14:38
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:14:38
User entered '28 Jul 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:14:38
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:14:03
User opened query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 22:14:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 22:14:03
User entered '30 Jun 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:14:03
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:19

US3272026

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	01 Aug 2020 14:39:11

US3272026

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:19
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:16:46

US3272026

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	01 Aug 2020 15:16:46

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered (b) (6) 1974'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:39:12

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '46'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '46'	System	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered 'Male (M)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered 'I'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

If race is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2020'	System	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Aug 2020 14:39:11

US3272026

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Aug 2020 15:17:27

US3272026

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:43
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:27

US3272026

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:54:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:45
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:20:10

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 16:22:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 16:22:04
Data point term sent to Coder	System	01 Aug 2020 16:21:31
User entered 'seasonal allergies'	Ashley Bell (b) (4)	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2013'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2013'	System	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 16:22:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 16:22:04
Data point term sent to Coder	System	01 Aug 2020 16:21:33
User entered 'Vasectomy'	Ashley Bell (b) (4) (b) (4)	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	Ashley Bell (b) (4)	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:21:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 16:21:08
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:21:08
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:21:02
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2002'	Ashley Bell (b) (4)	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2002'	System	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Jan 2002'	System	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2002'	System	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Cutaneous neoplasms benign, HLT: Skin neoplasms benign, PT: Acrochordon, LLT: Skin tags - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 13:48:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 13:48:16
Data point term sent to Coder	System	01 Aug 2020 16:22:34
User entered 'Bilateral Axillary Skin Tags'	Ashley Bell (b) (4) (b) (4)	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2010'	System	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:06
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:09
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:09
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'vitals in visit 1 day 1 as screening was done same day' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:42:36
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:54:35
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:08
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:11
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:45:09
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	10 Sep 2020 15:45:09
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:44:57
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:44:57
User entered '01 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:44:57
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:17:01
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	09 Sep 2020 22:17:01
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:17:01
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 22:17:01

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Jul 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:17:01
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:16:09
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:15:11
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	09 Sep 2020 22:15:11
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:14:03
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 16:29:45
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:29:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 16:29:36
User entered '01 Dec ' (non-conformant).	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:10
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:15
User entered '08:47' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:41
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered '08:47'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 08:47'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered '01 Aug 2020 08:47'	System	10 Sep 2020 15:44:57
User entered '28 Jul 2020 08:47'	System	09 Sep 2020 22:17:01
User entered '01 Aug 2020 08:47'	System	01 Aug 2020 16:29:45
User entered '01 Dec 08:47' (non-conformant).	System	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Height (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:12
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:18
User entered '185.0' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:59
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 16:32:50
User entered '185.0' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:32:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 16:30:46
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 16:30:46
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Aug 2020 16:30:46
User entered '185' (non-conformant).	Ashley Bell (b) (4)	01 Aug 2020 16:30:46
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 16:29:36
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:29:36
DataPoint set to visible.	System	01 Aug 2020 15:17:27

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Weight (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:14
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:22
User entered '123.2' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:47:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered '123.2' kg	Ashley Bell (b) (4)	01 Aug 2020 16:29:36
DataPoint set to visible.	System	01 Aug 2020 15:17:27

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '35.99708'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered '36.0'	System	01 Aug 2020 16:32:50
User entered empty.	System	01 Aug 2020 16:29:36
DataPoint set to visible.	System	01 Aug 2020 15:17:27

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'kg/m2'	System	01 Aug 2020 16:32:50
User entered empty.	System	01 Aug 2020 16:29:36
DataPoint set to visible.	System	01 Aug 2020 15:17:27

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done "to avoid duplication. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:17
Query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done "to avoid duplication. Please update these fields as per CCGs.'	Ashley Bell (b) (4)	30 Sep 2020 18:11:26
answered with 'updated ' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done "to avoid duplication. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:47:32
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:47:32
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 23:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 20:25:07

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered '36.7' C	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered 'Other (Other)'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered 'tympanic'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered '78'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'bpm'	System	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered '24'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'breaths/min'	System	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered '144' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:33:22
User entered '143'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'mmHg'	System	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User closed query 'Re-Query : Please confirm if this can be reported as an AE. If so, please report on the AE form, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 06:28:39
Query 'Re-Query : Please confirm if this can be reported as an AE. If so, please report on the AE form, else clarify. Thank you.' answered with 'NO AE' (Site from DM).	Ashley Bell (b) (4)	15 Aug 2020 13:56:29
User opened query 'Re-Query : Please confirm if this can be reported as an AE. If so, please report on the AE form, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Aug 2020 14:54:17
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 14:40:34
User entered '90' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:33:22
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Ashley Bell (b) (4)	01 Aug 2020 16:32:03
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	01 Aug 2020 16:29:36
User entered '103'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'mmHg'	System	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	11 Sep 2020 14:06:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:06:49
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:59
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:33:35

US3272026

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 14:06:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:06:49
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:19:02
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 16:19:02
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	09 Sep 2020 16:19:02
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:19:02
User entered '01 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:19:02
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:18:55
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 16:18:55
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:18:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:55
User entered '02 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:18:55
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 23:11:27
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:59
User entered '01 Aug 2020'	Ashley Bell (b) (4)	01 Aug 2020 16:33:35

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'I'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:53
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:21

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:53
User entered '01 Aug 2020'	Ashley Bell (b) (4)	01 Aug 2020 16:34:21

US3272026

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:53
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:21

US3272026

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	01 Aug 2020 16:34:21

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:44:13

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

What was the participant's randomization number?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:36:27
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:36:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 14:44:13
User entered '100363' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:44:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:44:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:17:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:01:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:25:57
User entered '185.0' cm	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:19
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:26:07
User entered '123.2' kg	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:17:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:01:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:25:57
User entered '185.0' cm	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:19
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:26:07
User entered '123.2' kg	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:36:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 16:36:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:35:15
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '08:47' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 08:47'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '24' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '144' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '90' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:17:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:01:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:25:57
User entered '185.0' cm	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:19
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:26:07
User entered '123.2' kg	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:37:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 16:37:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:35:15
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:25:28
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol correct' (Site from System).	Ashley Bell (b) (4)	01 Aug 2020 16:37:28
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		01 Aug 2020 16:37:16
User entered '10:42' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:42'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'tympanic' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '15' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '132' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '100' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:07
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:37:52

US3272026

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:07
User entered '01 Aug 2020'	Ashley Bell (b) (4)	01 Aug 2020 16:37:52

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).		15 Aug 2020 14:33:18
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	15 Aug 2020 14:33:18
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	01 Aug 2020 15:17:46
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:46

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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)	21 Aug 2020 15:58:17
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 15:17:46

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered '10:10'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:10'	System	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Aug 2020 14:33:18
User entered empty.	Kayla Flege (b) (4)	01 Aug 2020 15:17:46
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered 'ONCE'	System	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:38:25

US3272026

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020'	Ashley Bell (b) (4)	01 Aug 2020 16:38:25

US3272026

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:26'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:38:25

US3272026

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 09:26'	System	01 Aug 2020 16:38:25

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '01 Aug 2020'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:20'	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '01 Aug 2020 09:20'	System	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:38:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 16:38:51
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:38:51
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:38:46
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Ashley Bell (b) (4) [REDACTED]	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:16
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:44:43

US3272026

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Aug 2020 16:44:43

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:49:58', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '515ed730-f1e6-4fcc-bd5c-12c768f7c6e9'	System	01 Aug 2020 15:50:25
User entered 'Yes (Y)'	System	01 Aug 2020 15:50:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '515ed730-f1e6-4fcc-bd5c-12c768f7c6e9'	System	01 Aug 2020 15:50:25
User entered '98.2'	System	01 Aug 2020 15:50:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '515ed730-f1e6-4fcc-bd5c-12c768f7c6e9'	System	01 Aug 2020 15:50:25
User entered 'No (N)'	System	01 Aug 2020 15:50:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '515ed730-f1e6-4fcc-bd5c-12c768f7c6e9'	System	01 Aug 2020 15:50:25
User entered '01 Aug 2020 10:50'	System	01 Aug 2020 15:50:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:30'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T00:59:49', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0f9e8182-4ded-47a1-b9f3-b35120a29166'	System	02 Aug 2020 06:03:44
User entered 'Yes (Y)'	System	02 Aug 2020 06:03:44

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0f9e8182-4ded-47a1-b9f3-b35120a29166'	System	02 Aug 2020 06:03:44
User entered '98.2'	System	02 Aug 2020 06:03:44

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0f9e8182-4ded-47a1-b9f3-b35120a29166'	System	02 Aug 2020 06:03:44
User entered 'No (N)'	System	02 Aug 2020 06:03:44

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0f9e8182-4ded-47a1-b9f3-b35120a29166'	System	02 Aug 2020 06:03:44
User entered '02 Aug 2020 01:03'	System	02 Aug 2020 06:03:44

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:55'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 2'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:04', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8f16ed-e665-41e4-a4c9-38c3bf039d8d'	System	03 Aug 2020 03:06:33
User entered 'Yes (Y)'	System	03 Aug 2020 03:06:33

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8f16ed-e665-41e4-a4c9-38c3bf039d8d'	System	03 Aug 2020 03:06:33
User entered '97.3'	System	03 Aug 2020 03:06:33

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8f16ed-e665-41e4-a4c9-38c3bf039d8d'	System	03 Aug 2020 03:06:33
User entered 'No (N)'	System	03 Aug 2020 03:06:33

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8f16ed-e665-41e4-a4c9-38c3bf039d8d'	System	03 Aug 2020 03:06:33
User entered '02 Aug 2020 22:06'	System	03 Aug 2020 03:06:33

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 3'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6d356c6d-fbac-4918-9922-875e1482d19c'	System	04 Aug 2020 02:07:50
User entered 'Yes (Y)'	System	04 Aug 2020 02:07:50

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6d356c6d-fbac-4918-9922-875e1482d19c'	System	04 Aug 2020 02:07:50
User entered '96.9'	System	04 Aug 2020 02:07:50

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:43', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6d356c6d-fbac-4918-9922-875e1482d19c'	System	04 Aug 2020 02:07:50
User entered 'No (N)'	System	04 Aug 2020 02:07:50

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:48', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6d356c6d-fbac-4918-9922-875e1482d19c'	System	04 Aug 2020 02:07:50
User entered '03 Aug 2020 21:07'	System	04 Aug 2020 02:07:50

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 4'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1130fafa-6e67-460e-9139-cb4bbd031317'	System	05 Aug 2020 01:41:25
User entered 'Yes (Y)'	System	05 Aug 2020 01:41:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1130fafa-6e67-460e-9139-cb4bbd031317'	System	05 Aug 2020 01:41:25
User entered '97.8'	System	05 Aug 2020 01:41:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1130fafa-6e67-460e-9139-cb4bbd031317'	System	05 Aug 2020 01:41:25
User entered 'No (N)'	System	05 Aug 2020 01:41:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1130fafa-6e67-460e-9139-cb4bbd031317'	System	05 Aug 2020 01:41:25
User entered '04 Aug 2020 20:41'	System	05 Aug 2020 01:41:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 5'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8fcacd-7bab-492c-b47b-ad1e247adf63'	System	06 Aug 2020 02:26:36
User entered 'Yes (Y)'	System	06 Aug 2020 02:26:36

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8fcacd-7bab-492c-b47b-ad1e247adf63'	System	06 Aug 2020 02:26:36
User entered '98.1'	System	06 Aug 2020 02:26:36

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8fcacd-7bab-492c-b47b-ad1e247adf63'	System	06 Aug 2020 02:26:36
User entered 'No (N)'	System	06 Aug 2020 02:26:36

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8fcacd-7bab-492c-b47b-ad1e247adf63'	System	06 Aug 2020 02:26:36
User entered '05 Aug 2020 21:26'	System	06 Aug 2020 02:26:36

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 6'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4cf56589-e516-4e47-98bc-c7352bb4225e'	System	07 Aug 2020 01:02:15
User entered 'Yes (Y)'	System	07 Aug 2020 01:02:15

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4cf56589-e516-4e47-98bc-c7352bb4225e' User entered '98.1'	System	07 Aug 2020 01:02:15
	System	07 Aug 2020 01:02:15

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4cf56589-e516-4e47-98bc-c7352bb4225e'	System	07 Aug 2020 01:02:15
User entered 'No (N)'	System	07 Aug 2020 01:02:15

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4cf56589-e516-4e47-98bc-c7352bb4225e'	System	07 Aug 2020 01:02:15
User entered '06 Aug 2020 18:56'	System	07 Aug 2020 01:02:15

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 7'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '20bc1072-075a-4a28-aa69-7abbe6a0ca1d'	System	07 Aug 2020 23:26:25
User entered 'Yes (Y)'	System	07 Aug 2020 23:26:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '20bc1072-075a-4a28-aa69-7abbe6a0ca1d' User entered '98.3'	System	07 Aug 2020 23:26:25
	System	07 Aug 2020 23:26:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '20bc1072-075a-4a28-aa69-7abbe6a0ca1d'	System	07 Aug 2020 23:26:25
User entered 'No (N)'	System	07 Aug 2020 23:26:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '20bc1072-075a-4a28-aa69-7abbe6a0ca1d'	System	07 Aug 2020 23:26:25
User entered '07 Aug 2020 17:26'	System	07 Aug 2020 23:26:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba'	System	01 Aug 2020 15:50:49
User entered 'None (1)'	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba'	System	01 Aug 2020 15:50:49
User entered 'No (N)'	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba'	System	01 Aug 2020 15:50:49
User entered 'No (N)'	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:43', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba' User entered 'None (1)'	System	01 Aug 2020 15:50:49
	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba' User entered '01 Aug 2020 10:50'	System	01 Aug 2020 15:50:49
	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:30'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee'	System	02 Aug 2020 06:04:10
User entered 'None (1)'	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee'	System	02 Aug 2020 06:04:10
User entered 'No (N)'	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:57', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee'	System	02 Aug 2020 06:04:10
User entered 'No (N)'	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee'	System	02 Aug 2020 06:04:10
User entered 'None (1)'	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:09', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee'	System	02 Aug 2020 06:04:10
User entered '02 Aug 2020 01:04'	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:55'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 2'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8'	System	03 Aug 2020 03:07:03
User entered 'None (1)'	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8'	System	03 Aug 2020 03:07:03
User entered 'No (N)'	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8'	System	03 Aug 2020 03:07:03
User entered 'No (N)'	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:51', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8'	System	03 Aug 2020 03:07:03
User entered 'None (1)'	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:01', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8'	System	03 Aug 2020 03:07:03
User entered '02 Aug 2020 22:07'	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 3'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:55', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f'	System	04 Aug 2020 02:08:10
User entered 'None (1)'	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f'	System	04 Aug 2020 02:08:10
User entered 'No (N)'	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f'	System	04 Aug 2020 02:08:10
User entered 'No (N)'	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f'	System	04 Aug 2020 02:08:10
User entered 'None (1)'	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f'	System	04 Aug 2020 02:08:10
User entered '03 Aug 2020 21:08'	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 4'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8'	System	05 Aug 2020 01:41:42
User entered 'None (1)'	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8'	System	05 Aug 2020 01:41:42
User entered 'No (N)'	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8'	System	05 Aug 2020 01:41:42
User entered 'No (N)'	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8'	System	05 Aug 2020 01:41:42
User entered 'None (1)'	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8'	System	05 Aug 2020 01:41:42
User entered '04 Aug 2020 20:41'	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 5'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6'	System	06 Aug 2020 02:26:48
User entered 'None (1)'	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6'	System	06 Aug 2020 02:26:48
User entered 'No (N)'	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6'	System	06 Aug 2020 02:26:48
User entered 'No (N)'	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6'	System	06 Aug 2020 02:26:48
User entered 'None (1)'	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6'	System	06 Aug 2020 02:26:48
User entered '05 Aug 2020 21:26'	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 6'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159'	System	07 Aug 2020 01:02:23
User entered 'None (1)'	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159'	System	07 Aug 2020 01:02:23
User entered 'No (N)'	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159'	System	07 Aug 2020 01:02:23
User entered 'No (N)'	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159'	System	07 Aug 2020 01:02:23
User entered 'None (1)'	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159'	System	07 Aug 2020 01:02:23
User entered '06 Aug 2020 18:56'	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 7'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187'	System	07 Aug 2020 23:26:50
User entered 'None (1)'	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187'	System	07 Aug 2020 23:26:50
User entered 'No (N)'	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187'	System	07 Aug 2020 23:26:50
User entered 'No (N)'	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187'	System	07 Aug 2020 23:26:50
User entered 'None (1)'	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:45', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187'	System	07 Aug 2020 23:26:50
User entered '07 Aug 2020 17:26'	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:53', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'None (0)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:55', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'None (0)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:58', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb'	System	01 Aug 2020 15:51:15
User entered 'None (0)'	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:01', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'None (0)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:04', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb'	System	01 Aug 2020 15:51:15
User entered 'None (0)'	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb'	System	01 Aug 2020 15:51:15
User entered 'None (0)'	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb'	System	01 Aug 2020 15:51:15
User entered 'No (N)'	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb'	System	01 Aug 2020 15:51:15
User entered '01 Aug 2020 10:51'	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 10:30'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e'	System	02 Aug 2020 06:04:39
User entered 'None (0)'	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e'	System	02 Aug 2020 06:04:39
User entered 'None (0)'	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e'	System	02 Aug 2020 06:04:39
User entered 'None (0)'	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e'	System	02 Aug 2020 06:04:39
User entered 'None (0)'	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e'	System	02 Aug 2020 06:04:39
User entered 'None (0)'	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e'	System	02 Aug 2020 06:04:39
User entered 'None (0)'	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e'	System	02 Aug 2020 06:04:39
User entered 'No (N)'	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:37', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e'	System	02 Aug 2020 06:04:39
User entered '02 Aug 2020 01:04'	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Aug 2020 13:55'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 2'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered 'None (0)'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered 'None (0)'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered 'None (0)'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered 'None (0)'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:08:00', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered 'None (0)'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:08:03', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered 'None (0)'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:08:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered 'No (N)'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:08:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered '02 Aug 2020 22:08'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 3'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85'	System	04 Aug 2020 02:08:45
User entered 'None (0)'	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85'	System	04 Aug 2020 02:08:45
User entered 'None (0)'	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85'	System	04 Aug 2020 02:08:45
User entered 'None (0)'	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85'	System	04 Aug 2020 02:08:45
User entered 'None (0)'	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85'	System	04 Aug 2020 02:08:45
User entered 'None (0)'	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85'	System	04 Aug 2020 02:08:45
User entered 'None (0)'	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85'	System	04 Aug 2020 02:08:45
User entered 'No (N)'	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85'	System	04 Aug 2020 02:08:45
User entered '03 Aug 2020 21:08'	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 4'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9'	System	05 Aug 2020 01:42:02
User entered 'None (0)'	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9'	System	05 Aug 2020 01:42:02
User entered 'None (0)'	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9'	System	05 Aug 2020 01:42:02
User entered 'None (0)'	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:49', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9'	System	05 Aug 2020 01:42:02
User entered 'None (0)'	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:51', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9'	System	05 Aug 2020 01:42:02
User entered 'None (0)'	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:53', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9'	System	05 Aug 2020 01:42:02
User entered 'None (0)'	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9'	System	05 Aug 2020 01:42:02
User entered 'No (N)'	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9'	System	05 Aug 2020 01:42:02
User entered '04 Aug 2020 20:41'	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 5'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520'	System	06 Aug 2020 02:27:10
User entered 'None (0)'	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520'	System	06 Aug 2020 02:27:10
User entered 'None (0)'	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:54', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520'	System	06 Aug 2020 02:27:10
User entered 'None (0)'	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520'	System	06 Aug 2020 02:27:10
User entered 'None (0)'	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:27:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520'	System	06 Aug 2020 02:27:10
User entered 'None (0)'	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:27:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520'	System	06 Aug 2020 02:27:10
User entered 'None (0)'	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:27:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520'	System	06 Aug 2020 02:27:10
User entered 'No (N)'	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:27:09', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520'	System	06 Aug 2020 02:27:10
User entered '05 Aug 2020 21:27'	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 6'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'None (0)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'None (0)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'None (0)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:09', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'None (0)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:12', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'None (0)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'None (0)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'No (N)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered '06 Aug 2020 18:57'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 7'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e'	System	07 Aug 2020 23:27:32
User entered 'None (0)'	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e'	System	07 Aug 2020 23:27:32
User entered 'None (0)'	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:04', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e'	System	07 Aug 2020 23:27:32
User entered 'None (0)'	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered 'None (0)'	System	07 Aug 2020 23:27:32
	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e'	System	07 Aug 2020 23:27:32
User entered 'None (0)'	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e'	System	07 Aug 2020 23:27:32
User entered 'None (0)'	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e'	System	07 Aug 2020 23:27:32
User entered 'No (N)'	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered '07 Aug 2020 17:27'	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:35
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:14:54

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:35
User entered '10 Aug 2020'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:14:54

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:35
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:14:54

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:35
User entered empty.	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:14:54

US3272026

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:15:27

US3272026

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Aug 2020 00:15:27

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:36:09

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '17 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 18:36:09

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Aug 2020 18:36:09

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 18:36:09

US3272026

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 18:35:56

US3272026

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 18:35:56

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:06:04

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Aug 2020 19:06:31
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	28 Aug 2020 19:06:31
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 19:06:31
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Aug 2020 19:06:04
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:06:04

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Aug 2020 19:06:04

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 19:06:04

US3272026

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 19:06:40

US3272026

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Aug 2020 19:06:40

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:11:27

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 09:30:45
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirm correct' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 18:14:21
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:31:24
Amendment Manager: User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 23:40:21
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 17:27:11
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'PROTOCOL DEVIATION NOTED' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 23:12:48
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Sep 2020 23:11:27
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:11:27

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 23:11:27

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	08 Sep 2020 23:11:27

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '10:26'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 10:26'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '137'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '88'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '12:05'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 12:05'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '88'	(b) (4), (b) (6)	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:14:13

US3272026

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:14:13

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '08 Sep 2020'	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '11:33'	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:33'	System	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:14:26

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:14:26

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:46'	(b) (4), (b) (6)	08 Sep 2020 23:14:26

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 10:46'	System	08 Sep 2020 23:14:26

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:36'	(b) (4), (b) (6)	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '8 Sep 2020 10:36'	System	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 23:14:43

US3272026

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Sep 2020 23:14:43

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:05:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '03d189c1-063f-484b-a8f0-f3a9b02bdeaa'	System	08 Sep 2020 17:05:54
User entered 'Yes (Y)'	System	08 Sep 2020 17:05:54

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:05:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '03d189c1-063f-484b-a8f0-f3a9b02bdeaa'	System	08 Sep 2020 17:05:54
User entered '97.9'	System	08 Sep 2020 17:05:54

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:05:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '03d189c1-063f-484b-a8f0-f3a9b02bdeaa'	System	08 Sep 2020 17:05:54
User entered 'No (N)'	System	08 Sep 2020 17:05:54

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:05:33', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '03d189c1-063f-484b-a8f0-f3a9b02bdeaa'	System	08 Sep 2020 17:05:54
User entered '08 Sep 2020 12:05'	System	08 Sep 2020 17:05:54

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:23'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:24:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '83584288-c081-451b-8f1a-29f99afd4d3c'	System	09 Sep 2020 01:25:14
User entered 'Yes (Y)'	System	09 Sep 2020 01:25:14

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '83584288-c081-451b-8f1a-29f99afd4d3c'	System	09 Sep 2020 01:25:14
User entered '97.5'	System	09 Sep 2020 01:25:14

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '83584288-c081-451b-8f1a-29f99afd4d3c'	System	09 Sep 2020 01:25:14
User entered 'No (N)'	System	09 Sep 2020 01:25:14

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:12', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '83584288-c081-451b-8f1a-29f99afd4d3c'	System	09 Sep 2020 01:25:14
User entered '08 Sep 2020 20:25'	System	09 Sep 2020 01:25:14

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 15:18'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 2'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:02:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd038f6a9-c1c5-4167-9cb0-37f9f65dcb6f' User entered 'Yes (Y)'	System	09 Sep 2020 21:03:03
	System	09 Sep 2020 21:03:03

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:02:51', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd038f6a9-c1c5-4167-9cb0-37f9f65dcb6f' User entered '98.5'	System	09 Sep 2020 21:03:03

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:02:55', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd038f6a9-c1c5-4167-9cb0-37f9f65dcb6f'	System	09 Sep 2020 21:03:03
User entered 'No (N)'	System	09 Sep 2020 21:03:03

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:02:58', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd038f6a9-c1c5-4167-9cb0-37f9f65dcb6f' User entered '09 Sep 2020 16:02'	System	09 Sep 2020 21:03:03
	System	09 Sep 2020 21:03:03

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 3'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:20', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8bb15bcc-bac7-4d6f-b2f0-9bcb39942721'	System	11 Sep 2020 04:40:39
User entered 'Yes (Y)'	System	11 Sep 2020 04:40:39

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8bb15bcc-bac7-4d6f-b2f0-9bcb39942721'	System	11 Sep 2020 04:40:39
User entered '97.9'	System	11 Sep 2020 04:40:39

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:33', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8bb15bcc-bac7-4d6f-b2f0-9bcb39942721'	System	11 Sep 2020 04:40:39
User entered 'No (N)'	System	11 Sep 2020 04:40:39

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:37', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8bb15bcc-bac7-4d6f-b2f0-9bcb39942721' User entered '10 Sep 2020 23:40'	System	11 Sep 2020 04:40:39
	System	11 Sep 2020 04:40:39

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 4'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:37', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '96b240d6-e04e-4bbf-8cf0-ec5ccb391dcd' User entered 'Yes (Y)'	System	11 Sep 2020 20:25:55

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '96b240d6-e04e-4bbf-8cf0-ec5ccb391dcd' User entered '98.1'	System	11 Sep 2020 20:25:55
	System	11 Sep 2020 20:25:55

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '96b240d6-e04e-4bbf-8cf0-ec5ccb391dcd'	System	11 Sep 2020 20:25:55
User entered 'No (N)'	System	11 Sep 2020 20:25:55

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '96b240d6-e04e-4bbf-8cf0-ec5ccb391dcd' User entered '11 Sep 2020 15:25'	System	11 Sep 2020 20:25:55
	System	11 Sep 2020 20:25:55

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 5'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:11:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'fddade9a-35ea-4bf0-82d5-99a9e752ce38'	System	12 Sep 2020 17:12:15
User entered 'Yes (Y)'	System	12 Sep 2020 17:12:15

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'fddade9a-35ea-4bf0-82d5-99a9e752ce38'	System	12 Sep 2020 17:12:15
User entered '97.9'	System	12 Sep 2020 17:12:15

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:09', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'fddade9a-35ea-4bf0-82d5-99a9e752ce38'	System	12 Sep 2020 17:12:15
User entered 'No (N)'	System	12 Sep 2020 17:12:15

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'fddade9a-35ea-4bf0-82d5-99a9e752ce38'	System	12 Sep 2020 17:12:15
User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:12:15

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 6'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '942c8e2c-12d9-45c4-89f8-8eb95f62d890'	System	13 Sep 2020 17:02:19
User entered 'Yes (Y)'	System	13 Sep 2020 17:02:19

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '942c8e2c-12d9-45c4-89f8-8eb95f62d890'	System	13 Sep 2020 17:02:19
User entered '97.9'	System	13 Sep 2020 17:02:19

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '942c8e2c-12d9-45c4-89f8-8eb95f62d890'	System	13 Sep 2020 17:02:19
User entered 'No (N)'	System	13 Sep 2020 17:02:19

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '942c8e2c-12d9-45c4-89f8-8eb95f62d890'	System	13 Sep 2020 17:02:19
User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:19

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 7'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9a717db6-89e1-4430-a3bd-a51929adc6d1' User entered 'Yes (Y)'	System	14 Sep 2020 23:46:24

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9a717db6-89e1-4430-a3bd-a51929adc6d1' User entered '98.1'	System	14 Sep 2020 23:46:24
	System	14 Sep 2020 23:46:24

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:18', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9a717db6-89e1-4430-a3bd-a51929adc6d1'	System	14 Sep 2020 23:46:24
User entered 'No (N)'	System	14 Sep 2020 23:46:24

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:20', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9a717db6-89e1-4430-a3bd-a51929adc6d1' User entered '14 Sep 2020 18:46'	System	14 Sep 2020 23:46:24
	System	14 Sep 2020 23:46:24

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106'	System	08 Sep 2020 17:09:24
User entered 'None (1)'	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106'	System	08 Sep 2020 17:09:24
User entered 'No (N)'	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106'	System	08 Sep 2020 17:09:24
User entered 'No (N)'	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:18', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106'	System	08 Sep 2020 17:09:24
User entered 'None (1)'	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106' User entered '08 Sep 2020 12:09'	System	08 Sep 2020 17:09:24
	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:23'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea' User entered 'None (1)'	System	09 Sep 2020 01:26:03
	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea'	System	09 Sep 2020 01:26:03
User entered 'No (N)'	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea' User entered 'No (N)'	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea' User entered 'None (1)'	System	09 Sep 2020 01:26:03
	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:00', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea' User entered '08 Sep 2020 20:26'	System	09 Sep 2020 01:26:03
	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 15:18'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 2'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:03', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6'	System	09 Sep 2020 21:03:18
User entered 'None (1)'	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6'	System	09 Sep 2020 21:03:18
User entered 'No (N)'	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6'	System	09 Sep 2020 21:03:18
User entered 'No (N)'	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6'	System	09 Sep 2020 21:03:18
User entered 'None (1)'	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6'	System	09 Sep 2020 21:03:18
User entered '09 Sep 2020 16:03'	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 3'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12'	System	11 Sep 2020 04:40:56
User entered 'None (1)'	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:45', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12'	System	11 Sep 2020 04:40:56
User entered 'No (N)'	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12'	System	11 Sep 2020 04:40:56
User entered 'No (N)'	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12'	System	11 Sep 2020 04:40:56
User entered 'None (1)'	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:55', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12'	System	11 Sep 2020 04:40:56
User entered '10 Sep 2020 23:40'	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 4'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee'	System	11 Sep 2020 20:26:09
User entered 'None (1)'	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee' User entered 'No (N)'	System	11 Sep 2020 20:26:09
	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee' User entered 'No (N)'	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee' User entered 'None (1)'	System	11 Sep 2020 20:26:09
	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee' User entered '11 Sep 2020 15:26'	System	11 Sep 2020 20:26:09
	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 5'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391'	System	12 Sep 2020 17:12:26
User entered 'None (1)'	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391'	System	12 Sep 2020 17:12:26
User entered 'No (N)'	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391'	System	12 Sep 2020 17:12:26
User entered 'No (N)'	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391' User entered 'None (1)'	System	12 Sep 2020 17:12:26
	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391'	System	12 Sep 2020 17:12:26
User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 6'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d'	System	13 Sep 2020 17:02:37
User entered 'None (1)'	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d'	System	13 Sep 2020 17:02:37
User entered 'No (N)'	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d'	System	13 Sep 2020 17:02:37
User entered 'No (N)'	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:48', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d'	System	13 Sep 2020 17:02:37
User entered 'None (1)'	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d' User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:37
	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 7'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9' User entered 'None (1)'	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9'	System	14 Sep 2020 23:46:38
User entered 'No (N)'	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:28', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9'	System	14 Sep 2020 23:46:38
User entered 'No (N)'	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9' User entered 'None (1)'	System	14 Sep 2020 23:46:38
	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9'	System	14 Sep 2020 23:46:38
User entered '14 Sep 2020 18:46'	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e'	System	08 Sep 2020 17:09:49
User entered 'None (0)'	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:28', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e'	System	08 Sep 2020 17:09:49
User entered 'None (0)'	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e'	System	08 Sep 2020 17:09:49
User entered 'None (0)'	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e'	System	08 Sep 2020 17:09:49
User entered 'None (0)'	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e'	System	08 Sep 2020 17:09:49
User entered 'None (0)'	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e'	System	08 Sep 2020 17:09:49
User entered 'None (0)'	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e'	System	08 Sep 2020 17:09:49
User entered 'No (N)'	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e'	System	08 Sep 2020 17:09:49
User entered '08 Sep 2020 12:09'	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 14:23'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:20', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:37', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:54', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:57', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a'	System	09 Sep 2020 01:27:16
User entered 'None (0)'	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a'	System	09 Sep 2020 01:27:16
User entered 'None (0)'	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:27:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a'	System	09 Sep 2020 01:27:16
User entered 'No (N)'	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:27:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a'	System	09 Sep 2020 01:27:16
User entered '08 Sep 2020 20:27'	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 15:18'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 2'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7'	System	09 Sep 2020 21:03:45
User entered 'None (0)'	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7'	System	09 Sep 2020 21:03:45
User entered 'None (0)'	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:28', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7'	System	09 Sep 2020 21:03:45
User entered 'None (0)'	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7'	System	09 Sep 2020 21:03:45
User entered 'None (0)'	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:33', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7'	System	09 Sep 2020 21:03:45
User entered 'None (0)'	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7'	System	09 Sep 2020 21:03:45
User entered 'None (0)'	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7'	System	09 Sep 2020 21:03:45
User entered 'No (N)'	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7'	System	09 Sep 2020 21:03:45
User entered '09 Sep 2020 16:03'	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 3'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:03', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801'	System	11 Sep 2020 04:41:33
User entered 'No interference with activity (1)'	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801'	System	11 Sep 2020 04:41:33
User entered 'None (0)'	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801'	System	11 Sep 2020 04:41:33
User entered 'None (0)'	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801'	System	11 Sep 2020 04:41:33
User entered 'None (0)'	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:18', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801'	System	11 Sep 2020 04:41:33
User entered 'None (0)'	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:20', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801'	System	11 Sep 2020 04:41:33
User entered 'None (0)'	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801'	System	11 Sep 2020 04:41:33
User entered 'No (N)'	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801'	System	11 Sep 2020 04:41:33
User entered '10 Sep 2020 23:41'	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 4'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f'	System	11 Sep 2020 20:26:29
User entered 'None (0)'	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f'	System	11 Sep 2020 20:26:29
User entered 'None (0)'	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'No (N)'	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered '11 Sep 2020 15:26'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 5'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c'	System	12 Sep 2020 17:12:43
User entered 'None (0)'	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:28', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c'	System	12 Sep 2020 17:12:43
User entered 'None (0)'	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c' User entered 'None (0)'	System	12 Sep 2020 17:12:43
	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c'	System	12 Sep 2020 17:12:43
User entered 'None (0)'	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c'	System	12 Sep 2020 17:12:43
User entered 'None (0)'	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c'	System	12 Sep 2020 17:12:43
User entered 'None (0)'	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c'	System	12 Sep 2020 17:12:43
User entered 'No (N)'	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c'	System	12 Sep 2020 17:12:43
User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 6'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65'	System	13 Sep 2020 17:02:59
User entered 'None (0)'	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:58', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65'	System	13 Sep 2020 17:02:59
User entered 'None (0)'	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:01', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65'	System	13 Sep 2020 17:02:59
User entered 'None (0)'	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:03', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65'	System	13 Sep 2020 17:02:59
User entered 'None (0)'	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65'	System	13 Sep 2020 17:02:59
User entered 'None (0)'	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65'	System	13 Sep 2020 17:02:59
User entered 'None (0)'	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65'	System	13 Sep 2020 17:02:59
User entered 'No (N)'	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65'	System	13 Sep 2020 17:02:59
User entered '13 Sep 2020 12:02'	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 7'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247'	System	14 Sep 2020 23:46:54
User entered 'None (0)'	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247'	System	14 Sep 2020 23:46:54
User entered 'None (0)'	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247'	System	14 Sep 2020 23:46:54
User entered 'None (0)'	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:43', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247'	System	14 Sep 2020 23:46:54
User entered 'None (0)'	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:45', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247'	System	14 Sep 2020 23:46:54
User entered 'None (0)'	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247'	System	14 Sep 2020 23:46:54
User entered 'None (0)'	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:49', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247'	System	14 Sep 2020 23:46:54
User entered 'No (N)'	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247'	System	14 Sep 2020 23:46:54
User entered '14 Sep 2020 18:46'	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 15:44:52

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 15:44:52

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 15:44:52

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 15:44:52

US3272026

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 15:44:54

US3272026

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 15:44:54

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:50:11

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 15:50:11

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 15:50:11

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 15:50:11

US3272026

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:50:14

US3272026

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 15:50:14

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:38:18

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	09 Oct 2020 18:38:18

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 18:38:18

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:38:18

US3272026

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:38:24

US3272026

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 18:38:24

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:38:42

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 18:38:42

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Oct 2020 18:38:42

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	09 Oct 2020 18:38:42

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '12:53'	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '9 Oct 2020 12:53'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Pulse (xxx)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136'	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '87'	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:39:40

US3272026

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 18:39:40

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:39:55

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 18:39:55

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:05'	(b) (4), (b) (6)	09 Oct 2020 18:39:55

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '9 Oct 2020 13:05'	System	09 Oct 2020 18:39:55

US3272026

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:39:59

US3272026

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 18:39:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 64'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-01T06:25:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0427386a-ff81-4a7d-9b7d-abbe8686b45a' User entered 'No (N)'	System	01 Oct 2020 11:25:57
	System	01 Oct 2020 11:25:57

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-01T06:25:45', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0427386a-ff81-4a7d-9b7d-abbe8686b45a' User entered 'No (N)'	System	01 Oct 2020 11:25:57
	System	01 Oct 2020 11:25:57

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-01T06:25:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0427386a-ff81-4a7d-9b7d-abbe8686b45a' User entered '01 Oct 2020 06:25:56'	System	01 Oct 2020 11:25:57
	System	01 Oct 2020 11:25:57

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '01 Oct 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '05 Oct 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 71'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-08T07:53:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '63b3ef3e-e7ea-41ed-b4ad-2c0f7210e6d5'	System	08 Oct 2020 12:53:29
User entered 'No (N)'	System	08 Oct 2020 12:53:29

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-08T07:53:18', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '63b3ef3e-e7ea-41ed-b4ad-2c0f7210e6d5'	System	08 Oct 2020 12:53:29
User entered 'No (N)'	System	08 Oct 2020 12:53:29

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-08T07:53:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '63b3ef3e-e7ea-41ed-b4ad-2c0f7210e6d5' User entered '08 Oct 2020 07:53:24'	System	08 Oct 2020 12:53:29
	System	08 Oct 2020 12:53:29

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '08 Oct 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '12 Oct 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 78'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-15T10:36:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f71f590-856e-4423-b6b1-b52340361eca' User entered 'No (N)'	System	15 Oct 2020 15:37:18
	System	15 Oct 2020 15:37:18

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-15T10:37:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f71f590-856e-4423-b6b1-b52340361eca' User entered 'No (N)'	System	15 Oct 2020 15:37:18
	System	15 Oct 2020 15:37:18

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-15T10:37:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f71f590-856e-4423-b6b1-b52340361eca' User entered '15 Oct 2020 10:37:14'	System	15 Oct 2020 15:37:18
	System	15 Oct 2020 15:37:18

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '15 Oct 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '19 Oct 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 92'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-29T07:10:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9790b8c1-a722-4a85-b5bb-cc30ee7e7cc9' User entered 'No (N)'	System	29 Oct 2020 12:11:05
	System	29 Oct 2020 12:11:05

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-29T07:10:48', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9790b8c1-a722-4a85-b5bb-cc30ee7e7cc9' User entered 'No (N)'	System	29 Oct 2020 12:11:05
	System	29 Oct 2020 12:11:05

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-29T07:11:00', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9790b8c1-a722-4a85-b5bb-cc30ee7e7cc9' User entered '29 Oct 2020 07:11:00'	System	29 Oct 2020 12:11:05
	System	29 Oct 2020 12:11:05

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '29 Oct 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '02 Nov 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 99'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-05T09:42:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ca73eb11-9aa1-4c2e-a09d-ec6ea778364e'	System	05 Nov 2020 15:42:36
User entered 'No (N)'	System	05 Nov 2020 15:42:36

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-05T09:42:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ca73eb11-9aa1-4c2e-a09d-ec6ea778364e'	System	05 Nov 2020 15:42:36
User entered 'No (N)'	System	05 Nov 2020 15:42:36

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-05T09:42:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ca73eb11-9aa1-4c2e-a09d-ec6ea778364e' User entered '05 Nov 2020 09:42:19'	System	05 Nov 2020 15:42:36
	System	05 Nov 2020 15:42:36

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '05 Nov 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '09 Nov 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 106'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered 'Yes (Y)'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'Yes (Y)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'Yes (Y)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '1'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '1'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430'	System	12 Nov 2020 17:45:42
User entered '1'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '1'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '1'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430' User entered '0'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:45:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:45:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-fffe32451430'	System	12 Nov 2020 17:45:42
User entered 'Yes (Y)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:45:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:45:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '12 Nov 2020 11:45:31'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '12 Nov 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '16 Nov 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '28 Sep 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '02 Oct 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Oct 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '09 Oct 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Oct 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '16 Oct 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Oct 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '23 Oct 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Oct 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '30 Oct 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '02 Nov 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '06 Nov 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '09 Nov 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '13 Nov 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered 'Yes (Y)'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered 'Yes (Y)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered '1'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered '1'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered '1'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered '1'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered '1'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '1'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered '1'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered '0'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered '0'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered '0'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[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.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:43', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '19 Nov 2020 08:40:43'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:18:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:18:24

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:54:31

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Please reconcile and add severity log as required. Of note 16Nov2020 subject O2 was 80% so ensure that is captured on severity page.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:59:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:03
Query 'Please reconcile and add severity log as required. Of note 16Nov2020 subject O2 was 80% so ensure that is captured on severity page.' answered with 'this was updated' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 14:50:30
User opened query 'Please reconcile and add severity log as required. Of note 16Nov2020 subject O2 was 80% so ensure that is captured on severity page.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:03:27
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:54:31

[Time of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:03
User entered '14:19'	(b) (4), (b) (6)	12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:54:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020 14:19'	System	12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:54:31

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:03
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4), (b) (6)	12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:54:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '8 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '9 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '100'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '97.4' F	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '13 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '97'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '98.5' F	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '14 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '97'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '101.5' F	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '15 Nov 2020'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '96'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '98.3' F	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '80'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '103.1' F	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '17 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:57:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:57:20
User entered 'UNK' (non-conformant).	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	17 Nov 2020 19:57:39
User entered empty.	System	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:57:39
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Nov 2020 19:57:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:57:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Nov 2020 19:57:01
User entered 'UNK' (non-conformant).	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '18 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '94'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	19 Nov 2020 21:55:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '100.2' F	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 21:55:01
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24
User entered 'Day 19 (Day 19)'	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '19 Nov 2020'	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'I'	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change:	Whitney West (b) (4)	20 Nov 2020 21:41:52
Data Entry Error	(b) (4)	
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:41:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 21:41:52
User entered '20 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	20 Nov 2020 21:41:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:41:24
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '1' reason for change: Data Entry Error	Whitney West (b) (4)	20 Nov 2020 21:41:52
User entered '0'	Whitney West (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4) (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User closed query 'Please reconcile and enter all missing fields. If not completed please mark each field as ND - Not Done' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 03:20:24
Query 'Please reconcile and enter all missing fields. If not completed please mark each field as ND - Not Done' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	23 Nov 2020 22:21:46
User opened query 'Please reconcile and enter all missing fields. If not completed please mark each field as ND - Not Done' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:33:59
User entered '21 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '0'	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '90'	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Nov 2020 16:01:59
User entered '98' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 16:01:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Nov 2020 16:00:57
User entered '98' (non-conformant).	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57
	(b) (4), (b) (6)	

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '22 Nov 2020'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '0'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '90'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '98.9' F	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 16 (Day 16)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '23 Nov 2020'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '0'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '68'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '98.3' F	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 10:54:31

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:02:02

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:33:59
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 'subject is positive' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 14:50:17
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	17 Nov 2020 19:44:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:44:44
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 21:02:02

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 10:54:31

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 19:44:44
User entered '0'	System	12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:08:36
User entered '17 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:08:36
User entered '17 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:08:36
User entered '28'	Whitney West (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Heart Rate](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Oxygen Saturation](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Clement (b) (4)	23 Nov 2020 23:44:59
	(b) (4)	
User entered '68' reason for change: New Information	Andrea Clement (b) (4)	23 Nov 2020 23:44:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '78'	Whitney West (b) (4)	19 Nov 2020 22:07:04
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[PaO2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[ECMO?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Clinical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Radiographical Evidence](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Date of Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[Start Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 10:54:31

[End Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:54:31

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:19
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:20

US3272026

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Please reconcile and enter saliva log' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 03:21:08
Query 'Please reconcile and enter saliva log' answered with 'Subject is in hospital, no saliva has been collected.' (Site from CRA).	Kayla Flege (b) (4)	23 Nov 2020 22:22:06
User opened query 'Please reconcile and enter saliva log' (Site from CRA).	(b) (4)	21 Nov 2020 19:28:01
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:28
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '13:10'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '12 Nov 2020 13:10'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '178' cm	(b) (4), (b) (6)	12 Nov 2020 21:11:05
DataPoint set to visible.	System	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '122.9' kg	(b) (4), (b) (6)	12 Nov 2020 21:11:05
DataPoint set to visible.	System	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '97.4' F	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '84'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '18'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '132'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '83'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:11:14

US3272026

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:55
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:11:14

US3272026

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:54:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:11:22

US3272026

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 10:54:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:59
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:11:22

US3272026

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:54:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:17
Query 'Please enter End of Study pages to reflect subject passed away on 17Nov2020' canceled (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 00:15:20
User opened query 'Please enter End of Study pages to reflect subject passed away on 17Nov2020' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 00:14:11
User signature succeeded.	Adam Brosz (b) (4)	17 Nov 2020 00:48:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 23:16:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 23:16:59
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:48
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:48:16

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:00
User entered 'USA-US070-2020-mRNA-1273-P301000019'	System	17 Nov 2020 19:10:49
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 19:10:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 19:50:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 19:50:50
Data point term sent to Coder	System	17 Nov 2020 19:50:17
Coding entries removed.	(b) (4), (b) (6)	17 Nov 2020 19:49:22
User entered 'COVID19' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:49:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 03:49:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 03:49:59
Data point term sent to Coder	System	16 Nov 2020 23:25:33
User entered 'Covid19 like illness'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'Please reconcile as there was an illness visit and subject has to be symptomatic to come in for illness visits' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 00:14:56
Query 'Please reconcile as there was an illness visit and subject has to be symptomatic to come in for illness visits' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 21:11:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 21:11:46
User opened query 'Please reconcile as there was an illness visit and subject has to be symptomatic to come in for illness visits' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:23:35
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '08 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
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)	20 Nov 2020 08:03:39
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 'updated' (Site from System).	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 21:12:01
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	16 Nov 2020 23:24:49
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Thanks for the response. Please update as soon as the data is available.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:05:23
Query 'Per CDM: Thanks for the response. Please update as soon as the data is available.' answered with 'Will do. Subject has not been discharged as of today.' (Site from DM).	Kayla Flege (b) (4) (b) (4)	24 Nov 2020 15:33:23
User opened query 'Per CDM: Thanks for the response. Please update as soon as the data is available.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:55:07
User closed query 'Per CDM: 'Subject is currently still hospitalized for recovery'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:54:48
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
Query 'Per CDM: 'Subject is currently still hospitalized for recovery'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' answered with 'subject is still currently in hospital' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:51:21
User opened query 'Per CDM: 'Subject is currently still hospitalized for recovery'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 08:03:36
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 21:51:16
User entered 'No (N)'	(b) (4)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '2' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 21:51:16
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:49:22
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'Please verify if PI feels this is related to IP' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 00:15:40
Query 'Please verify if PI feels this is related to IP' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	19 Nov 2020 21:12:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 21:11:46
User opened query 'Please verify if PI feels this is related to IP' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:22:21
User entered 'Related (RELATED)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'Please verify if PI feels this is related to study procedure as subject is >2 months from last dose' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 00:15:42
Query 'Please verify if PI feels this is related to study procedure as subject is >2 months from last dose' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 21:12:13
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 21:11:46
User opened query 'Please verify if PI feels this is related to study procedure as subject is >2 months from last dose' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:22:53
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 01:22:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 01:22:23
User entered 'Related (RELATED)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'None (NONE)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		19 Nov 2020 21:11:46
User entered '0' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 21:11:46
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	17 Nov 2020 19:49:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Nov 2020 23:27:58
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 23:27:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Nov 2020 23:24:49
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:49:22
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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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)	20 Nov 2020 15:45:44
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:49:22
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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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)	20 Nov 2020 15:45:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 21:51:16
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 Nov 2020 23:26:17
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	System	16 Nov 2020 23:26:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 23:24:49
User entered empty.	System	16 Nov 2020 23:24:49
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

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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)	20 Nov 2020 15:45:44
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Urgent PV Query: Describe signs and symptoms, and clinical course of the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:38:16
User closed query 'Urgent PV Query: Please provide relevant medical history, with onset date(s), severity, treatment and relevant details' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:38:06
User closed query 'Urgent PV Query: Please indicate any risk factors the subject had for the development of COVID-19, (advanced age, obesity, underlying cardiac conditions, congregate living, recent exposure, cancer, immunosuppression, hypertension, diabetes, asthma, other respiratory conditions, stressful situations, etc). ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:37:46
Query 'PV Urgent Query: Please send a hospital discharge summary and or pertinent consult notes 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 'subject is currently still in the hospital' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:56:50
Query 'Urgent PV Query: Has COVID-19 testing been repeated at any lab? Please provide dates and results of COVID-19 diagnostic testing (swab or other).' answered with 'went to pcp 11nov2020 tested and came back positive and started on steroids and then came for illness visit and was tested at study site12nov2020' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:56:15
Query 'Urgent PV Query: Describe signs and symptoms, and clinical course of the event.' answered with '08nov2020 symptoms started ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:55:10
Query 'Urgent PV Query: Please provide relevant medical history, with onset date(s), severity, treatment and relevant details' answered with 'in narrative' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:53:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
Query 'Urgent PV Query: Please indicate any risk factors the subject had for the development of COVID-19, (advanced age, obesity, underlying cardiac conditions, congregate living, recent exposure, cancer, immunosuppression, hypertension, diabetes, asthma, other respiratory conditions, stressful situations, etc). ' answered with 'obesity' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:52:34
Query 'Urgent PV Query: Please provide rationale for seriousness assessment of Life-threatening for event COVID19 -LIKE ILLNESS.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:01:15
Query 'Urgent PV Query: Please describe medical indication for hospitalization.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:00:37
Query 'PV Urgent 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.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:59:54
User opened query 'PV Urgent Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:44:03
Query 'Urgent PV Query: Please report the treatment received by the subject, including hospitalization and any procedures.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:51
Query 'Urgent PV Query: Please provide rationale for assessing the event COVID19 LIKE ILLNESS as possible related to both mRNA-1273 and Study procedure.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:42:11

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Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Urgent Query: Please send a hospital discharge summary and or pertinent consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:41:06
Query 'Urgent PV Query: Please provide results of pertinent consult notes if any or discharge summary when available and applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:40:55
User opened query 'Urgent PV Query: Has COVID-19 testing been repeated at any lab? Please provide dates and results of COVID-19 diagnostic testing (swab or other).' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:39:54
Query 'Urgent PV Query: Subject tested negative for COVID-19 on 12-Nov-2020. Has COVID-19 testing been repeated at any lab? Please provide dates and results of COVID-19 diagnostic testing (swab or other)' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:39:39
User opened query 'Urgent PV Query: Please report the treatment received by the subject, including hospitalization and any procedures.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:29:27
User opened query 'Urgent PV Query: Describe signs and symptoms, and clinical course of the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:29:00
User opened query 'Urgent PV Query: Please provide results of pertinent consult notes if any or discharge summary when available and applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:28:47
User opened query 'Urgent PV Query: Please provide relevant medical history, with onset date(s), severity, treatment and relevant details' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:28:27
User opened query 'Urgent PV Query: Please indicate any risk factors the subject had for the development of COVID-19, (advanced age, obesity, underlying cardiac conditions, congregate living, recent exposure, cancer, immunosuppression, hypertension, diabetes, asthma, other respiratory conditions, stressful situations, etc). ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:28:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Urgent PV Query: Please describe medical indication for hospitalization.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:27:52
User opened query 'Urgent PV Query: Subject tested negative for COVID-19 on 12-Nov-2020. Has COVID-19 testing been repeated at any lab? Please provide dates and results of COVID-19 diagnostic testing (swab or other)' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:27:40
User opened query 'Urgent PV Query: Please provide rationale for assessing the event COVID19 LIKE ILLNESS as possible related to both mRNA-1273 and Study procedure.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:27:30
User opened query 'Urgent PV Query: Please provide rationale for seriousness assessment of Life-threatening for event COVID19 -LIKE ILLNESS.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:27:15
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Nov 2020 21:51:16
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Nov 2020 21:51:16
User entered 'Pct called and reported O2 saturation in the 80s%. Directed patient to emergency department for sustained hypoxia. Found to be 78% on RA. Patient started on Bipap with O2 75% and transferred to ICU. Dx with acute respiratory failure, AKI, ARDs, and multifocal pneumonia.	Whitney West (b) (4) (b) (4)	19 Nov 2020 21:51:16
Was started on albuterol sulfate, deltasone, ceftriaxone, azithromycin, dexamethasone, exnoxaparin, remdesivir upon admission. Requesting further information.' reason for change: New Information		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Nov 2020 23:24:49
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 21:51:16
User entered '0'	System	16 Nov 2020 23:24:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:54:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:57
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Aug 2020 16:47:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Aug 2020 16:47:08
Data point term sent to Coder	System	01 Aug 2020 16:46:45
User entered 'fexofenadine'	Ashley Bell (b) (4) (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'seasonal allergies'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '30' reason for change: Data Entry Error	Kayla Flege (b) (4)	05 Sep 2020 04:50:50
User entered '1'	(b) (4)	
	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'You have noted a dose unite of "tablet" kindly enter the dose in mg if known.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 20:10:19
Query 'You have noted a dose unite of "tablet" kindly enter the dose in mg if known.' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 04:51:01
User entered 'mg (mg)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	05 Sep 2020 04:50:50
User opened query 'You have noted a dose unite of "tablet" kindly enter the dose in mg if known.' (Site from CRA).	(b) (4), (b) (6)	21 Aug 2020 16:03:33
User entered 'tablet (TABLET)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'as needed (PRN)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Oral (ORAL)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
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 23:40:50
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 'confirm correct' (Site from System).	Ashley Bell (b) (4)	01 Aug 2020 16:46:06
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	01 Aug 2020 16:45:49
User entered 'un UNK 2013'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 04:04:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 04:04:52
Data point term sent to Coder	System	19 Nov 2020 22:12:12
User entered 'Albuterol sulfate'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Wheezing'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '2.5'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'as needed (PRN)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, PRODUCT: ALL OTHER NON-THERAPEUTIC PRODUCTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 03:02:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 03:02:05
Data point term sent to Coder	System	23 Nov 2020 22:20:35
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	23 Nov 2020 22:20:25
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'updated' (Site from System).	Kayla Flege (b) (4) (b) (4)	23 Nov 2020 22:20:25
DataPoint Un-verified.	Kayla Flege (b) (4) (b) (4)	23 Nov 2020 22:20:21
User entered 'DELTASONE (Calcium Stearate, Corn Starch, Erythrosine Sodium, Lactose, Mineral Oil, Sorbic Acid and Sucrose.)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	23 Nov 2020 22:20:21
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:02:08
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	20 Nov 2020 15:50:17
Data point term sent to Coder	System	19 Nov 2020 22:13:13
Data point term sent to Coder	System	19 Nov 2020 22:12:12
User entered 'Deltasone'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'respiratory failure' reason for change:	Whitney West (b) (4)	19 Nov 2020 22:13:09
Data Entry Error	(b) (4)	
User entered '10'	Whitney West (b) (4)	19 Nov 2020 22:12:06
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered '10' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'mg (mg)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'once daily (QD)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Nov 2020 22:13:09
User entered '16 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	19 Nov 2020 22:12:06
User entered empty.	System	19 Nov 2020 22:12:06
	Whitney West (b) (4)	19 Nov 2020 22:12:06
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:13:09
User entered empty.	System	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:13:09
User entered empty.	System	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:13:09
User entered empty.	System	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:24:03
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 22:24:03
Data point term sent to Coder	System	19 Nov 2020 22:16:17
User entered 'Dexamethasone'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Acute hypoxic respiratory failure'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '20' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:23:06
User entered '10'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)' reason for change: New Information	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:23:06
User entered 'once (ONCE)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:23:06
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty; reason for change New Information	Whitney West (b) (4)	19 Nov 2020 22:23:06
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:23:06
User entered empty.	System	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:23:06
User entered empty.	System	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:23:06
User entered empty.	System	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:33:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:33:59
Data point term sent to Coder	System	19 Nov 2020 22:18:19
User entered 'Piperacillin-Tazobactam'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Bilateral pneumonia'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '3.375' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:29:50
User entered 'UNK'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:29:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:29:50
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:17:34
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once (ONCE)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:29:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:29:50
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:29:50
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:17:34
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:51:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:51:54
Data point term sent to Coder	System	19 Nov 2020 22:19:21
User entered 'Azithromycin'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Bilateral pneumonia'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '500' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:22:14
User entered 'UNK'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:22:14
User entered 'Other (OTHER)'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:22:14
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:19:07
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)' reason for change: New Information	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:22:14
User entered 'once (ONCE)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:22:14
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty; reason for change New Information	Whitney West (b) (4)	19 Nov 2020 22:22:14
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:22:14
User entered empty.	System	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:22:14
User entered empty.	System	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:22:14
User entered empty.	System	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:53:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:53:58
Data point term sent to Coder	System	19 Nov 2020 22:21:26
User entered 'Ceftriaxone'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Bilateral pneumonia'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '2'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'g (g)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:58:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 03:58:06
Data point term sent to Coder	System	19 Nov 2020 22:25:31
User entered 'Enoxaparin'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'DVT Prophylaxis'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '40'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Subcutaneous (SUBCUTANEOUS)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '17 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:27:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:27:09
Data point term sent to Coder	System	19 Nov 2020 22:26:32
User entered 'Remdesivir'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Covid 19'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '100'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:54:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:51:27
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:47:33

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 19:52:34

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered 'Chest X ray'	(b) (4), (b) (6)	17 Nov 2020 19:52:34

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	17 Nov 2020 19:52:34

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:52:34

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:54:31

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered '16 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 19:52:56

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:54:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered 'CAT Scan'	(b) (4), (b) (6)	17 Nov 2020 19:52:56

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	17 Nov 2020 19:52:56

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:54:31

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:52:56

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:54:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered '17 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 19:53:18

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:54:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered 'Chest X Ray'	(b) (4), (b) (6)	17 Nov 2020 19:53:18

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	17 Nov 2020 19:53:18

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 10:54:31

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:40:30
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 19:53:18

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:54:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered '17/Nov/2020 14:11'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:54:31

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)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:54:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered '18/Nov/2020 10:47'	System	18 Nov 2020 15:47:46

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:54:31

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)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 15:47:46

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:54:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 19:29:17
User entered '20/Nov/2020 15:02'	System	20 Nov 2020 20:02:04

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:54:31

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)	21 Nov 2020 19:29:17
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 20:02:04