

US3602111 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:09:46

All time stamps listed in this document are displayed in GMT

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Form: Participant Creation

Generated On: 26 Nov 2020 11:09:46

[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 11:09:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

Date of Birth (MMM yyyy)	(b) (6) 1984
Age	36
Age Units	YEARS
Age (Derived)	36
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

Date of Informed Consent (<i>dd MMM yyyy</i>)	29 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:46

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	29 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	8:53 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 8:53
Height (<i>xxx.x</i>)	66 in
Weight (<i>xxx.x</i>)	166 lb
BMI (<i>xxx.x</i>)	26.84912 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:46

Date of assessment (*dd MMM yyyy*) 29 SEP 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	29 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

(b) (6)

REGISTRANT

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

v6.020 DTW (1102)

12 of 1966

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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 11:09:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

What was the date of randomization? (dd MMM yyyy) 29 SEP 2020

What was the participant's randomization number? 115708

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:46

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 11:09:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	8:53 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 8:53
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 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 11:09:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:48
Temperature (xxx.x)	99 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

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: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 SEP 2020

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 10:15

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:46

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

29 SEP 2020

Collection time (*00:00-23:59*)

9:45 (24 HR)

Collection date and time (derived)

29 SEP 2020 9:45

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:46

Collection date (<i>dd MMM yyyy</i>)			29 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	9:45	29 SEP 2020 9:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

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 11:09:46

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 10:50

PC Open Date & Time

29 SEP 2020 10:35

PC Close Date & Time

29 SEP 2020 13:05

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

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 98.5 °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	29 SEP 2020 23:20
PC Open Date & Time	29 SEP 2020 14:00
PC Close Date & Time	30 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:46

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

97.9 °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

30 SEP 2020 22:58

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:46

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 03:50

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 06:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:46

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

99.3 °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

04 OCT 2020 08:53

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:46

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

98.3 °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

05 OCT 2020 05:17

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:46

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

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 05 OCT 2020 22:34

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

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

29 SEP 2020 10:51

PC Open Date & Time

29 SEP 2020 10:35

PC Close Date & Time

29 SEP 2020 13:05

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

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

29 SEP 2020 23:21

PC Open Date & Time

29 SEP 2020 14:00

PC Close Date & Time

30 SEP 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:46

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

30 SEP 2020 22:58

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:46

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

02 OCT 2020 03:50

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:46

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

03 OCT 2020 06:39

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:46

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

04 OCT 2020 08:53

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:46

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

05 OCT 2020 05:18

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:46

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

05 OCT 2020 22:35

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 10:51
PC Open Date & Time	29 SEP 2020 10:35
PC Close Date & Time	29 SEP 2020 13:05

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 23:21
PC Open Date & Time	29 SEP 2020 14:00
PC Close Date & Time	30 SEP 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

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 ☒

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

Yes ☐	
PC Time stamp	30 SEP 2020 22:58
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

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 ☒

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

Yes ☐	
PC Time stamp	02 OCT 2020 03:50
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

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 ☒

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

Yes ☐	
PC Time stamp	03 OCT 2020 06:39
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

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 ☒

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

Yes ☐	
PC Time stamp	04 OCT 2020 08:53
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

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 ☒

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

Yes ☐	
PC Time stamp	05 OCT 2020 05:18
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

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 ☒

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

Yes ☐	
PC Time stamp	05 OCT 2020 22:35
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3602111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

If Contact Not Made, please provide Comments

8:38 PM AND 9:10 PM - CALLED
TWICE WITHOUT SUCCESS.
VOICE MAILBOX IS FULL AND
WAS UNABLE TO LEAVE A
MESSAGE.

US3602111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

CALLS WERE MADE ON 10/13
AND 10/14 NO RESPONSE FROM
SUBJECT.

If Contact Not Made, please provide Comments

US3602111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT VOICEMAIL FOR SUBJECT
TO CALL BACK

If Contact Not Made, please provide Comments

US3602111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

DAY 145

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

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18 APR 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

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25 APR 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

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02 MAY 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

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04 JUL 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

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14 JUL 2022 00:01

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18 JUL 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

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28 JUL 2022 00:01

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01 AUG 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

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04 AUG 2022 00:01

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08 AUG 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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15 AUG 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

DAY 691

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

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22 AUG 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

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12 SEP 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2022 23:59

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2022 23:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:46

Date of Contact	26 OCT 2020
Time of Contact	14:29
Date and Time of Contact (derived)	26 OCT 2020 14:29
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☒
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.9 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	277 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.9 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	281 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	101 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	285 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	27 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	289 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	293 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	29 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	297 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	301 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	31 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	305 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	1 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	309 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	2 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	313 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	3 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	317 of 1966	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	4 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	321 of 1966	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	5 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	325 of 1966	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	6 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	329 of 1966	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	7 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	333 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	8 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	337 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	09 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	341 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

Symptom Day

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

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	10 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	345 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	349 of 1966	

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

Date of Visit	27 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Date of Test	27 OCT 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date _____

End Date _____

Mechanical Ventilation? Yes ☐ No ☒

Start Date _____

End Date _____

ECMO? Yes ☐ No ☒

Start Date _____

End Date _____

Evidence of Shock:

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

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date _____

Hepatic Dysfunction? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☐

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

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

Start Date

End Date

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:09:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 11:09:46

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	29 OCT 2020
Day 5	Yes	31 OCT 2020
Day 7	Yes	2 NOV 2020
Day 9	Yes	4 NOV 2020
Day 14	Yes	09 NOV 2020
Day 21	Yes	16 NOV 2020
Day 28	Yes	23 NOV 2020

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	27 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	8:02 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 8:02
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	96 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	73 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 11:09:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

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Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:09:46

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

27 OCT 2020

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD28

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	8:35 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 8:35
Height (xxx.x)	66 in
Weight (xxx.x)	164 lb
Temperature (xxx.x)	97.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3602111

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:09:46

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:46

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 (6)

Generated On: 26 Nov 2020 11:09:46

AEID	
Adverse event	SWEATING
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	27 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

AEID	USA-US079-2020-MRNA-1273-P30 1000003
Adverse event	SYMPTOMATIC COVID -19
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☒ No ☐
Start date (dd MMM yyyy)	24 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	23 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☒ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS EXPOSED TO COVID+ PATIENT ON 10/23/2020
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:46

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

Yes ☒

No ☐

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

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1993
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

Name of Medication	CENTRUM
Prophylaxis	Yes ☒ No ☐
Indication	DIETARY SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	FEVER
Dose per administration	1200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☒ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		24 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		24 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	1200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	FEVER
Dose per administration	1200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		25 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

Name of Medication	IPUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	800
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:46

[Were any concomitant procedures performed?](#)

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

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

Case Report Form

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

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

All	False
Date of missed or out of window visit or assessment	27 OCT 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	True
Missed Visit	True
Missed Assessment	True
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	False
Other, specify	
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3602111

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:46

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

US3602111

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:46

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 ☐

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

SAEID	USA-US079-2020-MRNA-1273-P301000003
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:46

SAEID	USA-US079-2020-MRNA-1273-P301000003
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/NOV/2020 19:00
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

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:09:46

SAEID	USA-US079-2020-MRNA-1273-P301000003
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/NOV/2020 00:29
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

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:09:46

SAEID	USA-US079-2020-MRNA-1273-P301000003
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	BINDU
Investigator's Last Name	BALANI
Site Address: Street	
Site Address: City	
Site Address: State	NJ
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/NOV/2020 07:47
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.	True

Audit

US3602111 (Prod: Hackensack University Medical Center)

US3602111

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:46

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3602111'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Sep 2020 12:52:49

US3602111

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:07:47

US3602111

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Sep 2020 12:52:50

US3602111

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Sep 2020 14:07:47

US3602111

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	29 Sep 2020 14:07:47

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1984'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Sep 2020 12:52:51

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Age](#)

Audit	User	Time (GMT)
User entered '36'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '36'	System	29 Sep 2020 14:08:24

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:46

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:08:11

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:08:24

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	29 Sep 2020 14:08:24

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '2020'	System	29 Sep 2020 14:08:24

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	29 Sep 2020 14:08:24

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:08:24

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:08:24

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:08:24

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:08:24

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	29 Sep 2020 12:52:50

US3602111

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 14:08:35

US3602111

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:08:35

US3602111

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:08:59

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:11:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:11:53
Data point term sent to Coder	System	29 Sep 2020 14:10:55
User entered 'Asthma'	(b) (4), (b) (6) (b) (4)	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'UN UNK 1993'	(b) (4), (b) (6)	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Jan 1993'	System	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '1993'	System	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:09:54

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '8:53'	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 8:53'	System	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '66' in	(b) (4), (b) (6)	29 Sep 2020 14:10:46
DataPoint set to visible.	System	29 Sep 2020 14:08:35

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '166' lb	(b) (4), (b) (6)	29 Sep 2020 14:10:46
DataPoint set to visible.	System	29 Sep 2020 14:08:35

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '26.84912'	System	29 Sep 2020 14:10:46
DataPoint set to visible.	System	29 Sep 2020 14:08:35

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	29 Sep 2020 14:10:46
DataPoint set to visible.	System	29 Sep 2020 14:08:35

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 14:10:46

US3602111

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:10:53

US3602111

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:10:53

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:46

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:46

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:09:46

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:11:05

US3602111

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

US3602111

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

US3602111

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

US3602111

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

US3602111

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:11:19

US3602111

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:19

US3602111

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:11:19

US3602111

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:11:19

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

[Specify](#)

Audit		User	Time (GMT)
User entered	(b) (6)	Registrant'	(b) (4), (b) (6)
			29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

No Risk Identified

Audit	User	Time (GMT)
User closed query 'No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:05:26
User opened query 'No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	29 Sep 2020 14:20:04
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 21:05:26
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:46

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:20:04

US3602111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:20:15

US3602111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:20:15

US3602111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Sep 2020 14:20:15

US3602111

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	29 Sep 2020 14:20:15

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Sep 2020 13:07:55

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '115708'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Sep 2020 13:07:55

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	29 Sep 2020 13:07:55

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29

US3602111

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:20:29
DataPoint set to visible.	System	29 Sep 2020 14:08:24

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:46

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:46

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:46

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:46

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '8:53'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 8:53'	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '61'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '107'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:46

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:46

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 15:12:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 15:12:23
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 14:21:35
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '10:48' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:48'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99' F reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '16' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '104' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '68' reason for change: New Information	(b) (4), (b) (6)	29 Sep 2020 15:12:23
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Sep 2020 15:12:23
User entered empty.	System	29 Sep 2020 14:21:35

US3602111

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:21:43

US3602111

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:43

US3602111

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:21:47

US3602111

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

US3602111

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

US3602111

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Result](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

US3602111

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider entering "No" for this field as screening and V1D1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:16:02
Query 'Per CDM: Please consider entering "No" for this field as screening and V1D1 have occurred on the same day.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 16:12:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 16:12:53
User opened query 'Per CDM: Please consider entering "No" for this field as screening and V1D1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:16:04
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

US3602111

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

US3602111

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:21:47

US3602111

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:21:47

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '10:15'	(b) (4), (b) (6)	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:15'	System	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 14:22:08

US3602111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:22:20

US3602111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:22:20

US3602111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '9:45'	(b) (4), (b) (6)	29 Sep 2020 14:22:20

US3602111

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 9:45'	System	29 Sep 2020 14:22:20

US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:46

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '9:45'	(b) (4), (b) (6)	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '29 Sep 2020 9:45'	System	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:46

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:22:33

US3602111

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User closed query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 05:40:24
Query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' answered with 'Subject is now in the convalescent period following positive COVID-19 results. However, since the positive result is after the completed safety calls, this will remain yes and under safety call Day 22 continuing that will be changed to no. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 16:40:11
User opened query 'Per CDM: Is the participant continuing to the next visit? is 'YES' however, there is no further visits recorded, please review and confirm with a response. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 15:05:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:22:40

US3602111

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 14:22:40

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:26', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7ba34cbe-e67b-4893-b16b-c1bb29647128'	System	29 Sep 2020 14:50:52
User entered 'Yes (Y)'	System	29 Sep 2020 14:50:52

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:33', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7ba34cbe-e67b-4893-b16b-c1bb29647128'	System	29 Sep 2020 14:50:52
User entered '99.0'	System	29 Sep 2020 14:50:52

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:38', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7ba34cbe-e67b-4893-b16b-c1bb29647128'	System	29 Sep 2020 14:50:52
User entered 'No (N)'	System	29 Sep 2020 14:50:52

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:42', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7ba34cbe-e67b-4893-b16b-c1bb29647128'	System	29 Sep 2020 14:50:52
User entered '29 Sep 2020 10:50'	System	29 Sep 2020 14:50:52

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:35'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:05'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:20:46', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'af392203-5976-44a2-ac88-10188b073591'	System	30 Sep 2020 03:21:00
User entered 'Yes (Y)'	System	30 Sep 2020 03:21:00

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:20:50', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'af392203-5976-44a2-ac88-10188b073591'	System	30 Sep 2020 03:21:00
User entered '98.5'	System	30 Sep 2020 03:21:00

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:20:54', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'af392203-5976-44a2-ac88-10188b073591'	System	30 Sep 2020 03:21:00
User entered 'No (N)'	System	30 Sep 2020 03:21:00

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:20:58', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'af392203-5976-44a2-ac88-10188b073591'	System	30 Sep 2020 03:21:00
User entered '29 Sep 2020 23:20'	System	30 Sep 2020 03:21:00

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 2'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:57:56', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b1fa6dde-bf71-4fe7-86ce-d2bd02f4ed2c'	System	01 Oct 2020 02:58:08
User entered 'Yes (Y)'	System	01 Oct 2020 02:58:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:01', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b1fa6dde-bf71-4fe7-86ce-d2bd02f4ed2c'	System	01 Oct 2020 02:58:08
User entered '97.9'	System	01 Oct 2020 02:58:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:04', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b1fa6dde-bf71-4fe7-86ce-d2bd02f4ed2c'	System	01 Oct 2020 02:58:08
User entered 'No (N)'	System	01 Oct 2020 02:58:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:07', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b1fa6dde-bf71-4fe7-86ce-d2bd02f4ed2c'	System	01 Oct 2020 02:58:08
User entered '30 Sep 2020 22:58'	System	01 Oct 2020 02:58:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 3'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:49:45', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '143327cc-e79b-4ad6-98df-8bae62499350'	System	02 Oct 2020 07:50:17
User entered 'Yes (Y)'	System	02 Oct 2020 07:50:17

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:49:58', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '143327cc-e79b-4ad6-98df-8bae62499350'	System	02 Oct 2020 07:50:17
User entered '97.7'	System	02 Oct 2020 07:50:17

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:10', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '143327cc-e79b-4ad6-98df-8bae62499350'	System	02 Oct 2020 07:50:17
User entered 'No (N)'	System	02 Oct 2020 07:50:17

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '143327cc-e79b-4ad6-98df-8bae62499350'	System	02 Oct 2020 07:50:17
User entered '02 Oct 2020 03:50'	System	02 Oct 2020 07:50:17

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 4'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:00', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '874c4697-116c-4e99-8379-ae3dfae12cdc'	System	03 Oct 2020 10:39:14
User entered 'Yes (Y)'	System	03 Oct 2020 10:39:14

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:05', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '874c4697-116c-4e99-8379-ae3dfae12cdc' User entered '96.8'	System	03 Oct 2020 10:39:14

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:07', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '874c4697-116c-4e99-8379-ae3dfae12cdc'	System	03 Oct 2020 10:39:14
User entered 'No (N)'	System	03 Oct 2020 10:39:14

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:10', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '874c4697-116c-4e99-8379-ae3dfae12cdc' User entered '03 Oct 2020 06:39'	System	03 Oct 2020 10:39:14
	System	03 Oct 2020 10:39:14

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 5'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:52:57', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7c565997-b863-4aa6-9b5b-8a8f2173ce20'	System	04 Oct 2020 12:53:22
User entered 'Yes (Y)'	System	04 Oct 2020 12:53:22

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:00', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7c565997-b863-4aa6-9b5b-8a8f2173ce20'	System	04 Oct 2020 12:53:22
User entered '99.3'	System	04 Oct 2020 12:53:22

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:02', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7c565997-b863-4aa6-9b5b-8a8f2173ce20'	System	04 Oct 2020 12:53:22
User entered 'No (N)'	System	04 Oct 2020 12:53:22

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:20', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7c565997-b863-4aa6-9b5b-8a8f2173ce20'	System	04 Oct 2020 12:53:22
User entered '04 Oct 2020 08:53'	System	04 Oct 2020 12:53:22

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 6'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:44', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '684d244f-3506-47a7-8cd1-bd40ee5d62c5'	System	05 Oct 2020 09:17:54
User entered 'Yes (Y)'	System	05 Oct 2020 09:17:54

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:47', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '684d244f-3506-47a7-8cd1-bd40ee5d62c5'	System	05 Oct 2020 09:17:54
User entered '98.3'	System	05 Oct 2020 09:17:54

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:50', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '684d244f-3506-47a7-8cd1-bd40ee5d62c5'	System	05 Oct 2020 09:17:54
User entered 'No (N)'	System	05 Oct 2020 09:17:54

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:52', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '684d244f-3506-47a7-8cd1-bd40ee5d62c5'	System	05 Oct 2020 09:17:54
User entered '05 Oct 2020 05:17'	System	05 Oct 2020 09:17:54

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 7'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:44', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b515bab6-66c5-4bbf-b0c3-8b606a77e0d1'	System	06 Oct 2020 02:34:55
User entered 'Yes (Y)'	System	06 Oct 2020 02:34:55

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:48', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b515bab6-66c5-4bbf-b0c3-8b606a77e0d1'	System	06 Oct 2020 02:34:55
User entered '97.8'	System	06 Oct 2020 02:34:55

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:50', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b515bab6-66c5-4bbf-b0c3-8b606a77e0d1'	System	06 Oct 2020 02:34:55
User entered 'No (N)'	System	06 Oct 2020 02:34:55

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:52', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'b515bab6-66c5-4bbf-b0c3-8b606a77e0d1'	System	06 Oct 2020 02:34:55
User entered '05 Oct 2020 22:34'	System	06 Oct 2020 02:34:55

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:53', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318'	System	29 Sep 2020 14:51:08
User entered 'None (1)'	System	29 Sep 2020 14:51:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:56', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318'	System	29 Sep 2020 14:51:08
User entered 'No (N)'	System	29 Sep 2020 14:51:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:50:59', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318'	System	29 Sep 2020 14:51:08
User entered 'No (N)'	System	29 Sep 2020 14:51:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:02', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318'	System	29 Sep 2020 14:51:08
User entered 'None (1)'	System	29 Sep 2020 14:51:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:06', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'c2b804a0-1533-4601-b255-519b47ae5318'	System	29 Sep 2020 14:51:08
User entered '29 Sep 2020 10:51'	System	29 Sep 2020 14:51:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:35'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:05'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:06', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337'	System	30 Sep 2020 03:21:22
User entered 'None (1)'	System	30 Sep 2020 03:21:22

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:09', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337'	System	30 Sep 2020 03:21:22
User entered 'No (N)'	System	30 Sep 2020 03:21:22

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337'	System	30 Sep 2020 03:21:22
User entered 'No (N)'	System	30 Sep 2020 03:21:22

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337'	System	30 Sep 2020 03:21:22
User entered 'None (1)'	System	30 Sep 2020 03:21:22

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:19', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6f17913b-d1ac-4317-b80f-2ca95b1b3337'	System	30 Sep 2020 03:21:22
User entered '29 Sep 2020 23:21'	System	30 Sep 2020 03:21:22

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 2'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:12', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0'	System	01 Oct 2020 02:58:25
User entered 'None (1)'	System	01 Oct 2020 02:58:25

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:14', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0'	System	01 Oct 2020 02:58:25
User entered 'No (N)'	System	01 Oct 2020 02:58:25

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:17', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0'	System	01 Oct 2020 02:58:25
User entered 'No (N)'	System	01 Oct 2020 02:58:25

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:21', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0'	System	01 Oct 2020 02:58:25
User entered 'None (1)'	System	01 Oct 2020 02:58:25

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '12e29112-ce81-4cd1-bef9-97d293c367c0'	System	01 Oct 2020 02:58:25
User entered '30 Sep 2020 22:58'	System	01 Oct 2020 02:58:25

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 3'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcbb7-8ac9-4e0d-8274-8ce8d1bd314b'	System	02 Oct 2020 07:50:27
User entered 'None (1)'	System	02 Oct 2020 07:50:27

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:19', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcbb7-8ac9-4e0d-8274-8ce8d1bd314b'	System	02 Oct 2020 07:50:27
User entered 'No (N)'	System	02 Oct 2020 07:50:27

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:21', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcbb7-8ac9-4e0d-8274-8ce8d1bd314b'	System	02 Oct 2020 07:50:27
User entered 'No (N)'	System	02 Oct 2020 07:50:27

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcbb7-8ac9-4e0d-8274-8ce8d1bd314b'	System	02 Oct 2020 07:50:27
User entered 'None (1)'	System	02 Oct 2020 07:50:27

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:25', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '617bcbb7-8ac9-4e0d-8274-8ce8d1bd314b'	System	02 Oct 2020 07:50:27
User entered '02 Oct 2020 03:50'	System	02 Oct 2020 07:50:27

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 4'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d'	System	03 Oct 2020 10:39:26
User entered 'None (1)'	System	03 Oct 2020 10:39:26

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d'	System	03 Oct 2020 10:39:26
User entered 'No (N)'	System	03 Oct 2020 10:39:26

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:18', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d'	System	03 Oct 2020 10:39:26
User entered 'No (N)'	System	03 Oct 2020 10:39:26

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:20', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d'	System	03 Oct 2020 10:39:26
User entered 'None (1)'	System	03 Oct 2020 10:39:26

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:22', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '671ba37d-a4c1-49a2-b6a0-1953d277065d'	System	03 Oct 2020 10:39:26
User entered '03 Oct 2020 06:39'	System	03 Oct 2020 10:39:26

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 5'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:24', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered 'None (1)'	System	04 Oct 2020 12:53:38

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:26', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered 'No (N)'	System	04 Oct 2020 12:53:38

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:28', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered 'No (N)'	System	04 Oct 2020 12:53:38

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered 'None (1)'	System	04 Oct 2020 12:53:38

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:32', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '7805af07-b575-41ed-a01f-68e7ef673092'	System	04 Oct 2020 12:53:38
User entered '04 Oct 2020 08:53'	System	04 Oct 2020 12:53:38

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 6'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:54', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac'	System	05 Oct 2020 09:18:08
User entered 'None (1)'	System	05 Oct 2020 09:18:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:57', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac'	System	05 Oct 2020 09:18:08
User entered 'No (N)'	System	05 Oct 2020 09:18:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:17:59', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac'	System	05 Oct 2020 09:18:08
User entered 'No (N)'	System	05 Oct 2020 09:18:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:02', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac'	System	05 Oct 2020 09:18:08
User entered 'None (1)'	System	05 Oct 2020 09:18:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:04', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '01bca412-5fee-42eb-ab0f-6abdd805c3ac'	System	05 Oct 2020 09:18:08
User entered '05 Oct 2020 05:18'	System	05 Oct 2020 09:18:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 7'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:56', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a'	System	06 Oct 2020 02:35:09
User entered 'None (1)'	System	06 Oct 2020 02:35:09

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:34:58', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a'	System	06 Oct 2020 02:35:09
User entered 'No (N)'	System	06 Oct 2020 02:35:09

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:00', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a'	System	06 Oct 2020 02:35:09
User entered 'No (N)'	System	06 Oct 2020 02:35:09

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:02', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a'	System	06 Oct 2020 02:35:09
User entered 'None (1)'	System	06 Oct 2020 02:35:09

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:04', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1e626624-4847-48de-b969-4ea818939a5a'	System	06 Oct 2020 02:35:09
User entered '05 Oct 2020 22:35'	System	06 Oct 2020 02:35:09

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:17', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160'	System	29 Sep 2020 14:51:37
User entered 'None (0)'	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:20', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160'	System	29 Sep 2020 14:51:37
User entered 'None (0)'	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:22', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160'	System	29 Sep 2020 14:51:37
User entered 'None (0)'	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:24', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160'	System	29 Sep 2020 14:51:37
User entered 'None (0)'	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:27', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160'	System	29 Sep 2020 14:51:37
User entered 'None (0)'	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:29', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160'	System	29 Sep 2020 14:51:37
User entered 'None (0)'	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160'	System	29 Sep 2020 14:51:37
User entered 'No (N)'	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T10:51:34', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '3060a8c3-e694-4ffb-8e1c-5f00ecc58160'	System	29 Sep 2020 14:51:37
User entered '29 Sep 2020 10:51'	System	29 Sep 2020 14:51:37

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 10:35'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 13:05'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe'	System	30 Sep 2020 03:21:41
User entered 'None (0)'	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:25', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe'	System	30 Sep 2020 03:21:41
User entered 'None (0)'	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:27', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe'	System	30 Sep 2020 03:21:41
User entered 'None (0)'	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:29', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe'	System	30 Sep 2020 03:21:41
User entered 'None (0)'	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe'	System	30 Sep 2020 03:21:41
User entered 'None (0)'	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:33', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe'	System	30 Sep 2020 03:21:41
User entered 'None (0)'	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:37', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe'	System	30 Sep 2020 03:21:41
User entered 'No (N)'	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-29T23:21:39', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '023320b2-97ec-4a93-89fc-6e55202c07fe'	System	30 Sep 2020 03:21:41
User entered '29 Sep 2020 23:21'	System	30 Sep 2020 03:21:41

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 2'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:27', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed'	System	01 Oct 2020 02:58:45
User entered 'None (0)'	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:29', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed'	System	01 Oct 2020 02:58:45
User entered 'None (0)'	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed'	System	01 Oct 2020 02:58:45
User entered 'None (0)'	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:33', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed'	System	01 Oct 2020 02:58:45
User entered 'None (0)'	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:35', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed'	System	01 Oct 2020 02:58:45
User entered 'None (0)'	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:37', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed'	System	01 Oct 2020 02:58:45
User entered 'None (0)'	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:39', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed'	System	01 Oct 2020 02:58:45
User entered 'No (N)'	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-09-30T22:58:41', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '352f0616-5c39-447f-abce-0c2b354779ed'	System	01 Oct 2020 02:58:45
User entered '30 Sep 2020 22:58'	System	01 Oct 2020 02:58:45

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 3'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:27', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278'	System	02 Oct 2020 07:50:43
User entered 'None (0)'	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:29', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278'	System	02 Oct 2020 07:50:43
User entered 'None (0)'	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278'	System	02 Oct 2020 07:50:43
User entered 'None (0)'	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:33', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278'	System	02 Oct 2020 07:50:43
User entered 'None (0)'	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:34', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278'	System	02 Oct 2020 07:50:43
User entered 'None (0)'	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:36', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278'	System	02 Oct 2020 07:50:43
User entered 'None (0)'	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:38', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278'	System	02 Oct 2020 07:50:43
User entered 'No (N)'	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-02T03:50:40', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '6cf94337-03e9-43f8-aa27-189286255278' User entered '02 Oct 2020 03:50'	System	02 Oct 2020 07:50:43
	System	02 Oct 2020 07:50:43

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 4'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:25', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c'	System	03 Oct 2020 10:39:38
User entered 'None (0)'	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:26', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c'	System	03 Oct 2020 10:39:38
User entered 'None (0)'	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:28', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c'	System	03 Oct 2020 10:39:38
User entered 'None (0)'	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:30', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered 'None (0)'	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:31', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c'	System	03 Oct 2020 10:39:38
User entered 'None (0)'	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:32', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c'	System	03 Oct 2020 10:39:38
User entered 'None (0)'	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:34', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c'	System	03 Oct 2020 10:39:38
User entered 'No (N)'	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-03T06:39:36', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '1812476e-edd2-428f-9bd3-62251584588c' User entered '03 Oct 2020 06:39'	System	03 Oct 2020 10:39:38
	System	03 Oct 2020 10:39:38

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 5'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:35', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b'	System	04 Oct 2020 12:53:49
User entered 'None (0)'	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:37', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b'	System	04 Oct 2020 12:53:49
User entered 'None (0)'	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:38', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b'	System	04 Oct 2020 12:53:49
User entered 'None (0)'	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:39', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b'	System	04 Oct 2020 12:53:49
User entered 'None (0)'	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:41', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b'	System	04 Oct 2020 12:53:49
User entered 'None (0)'	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:42', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b'	System	04 Oct 2020 12:53:49
User entered 'None (0)'	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:43', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b'	System	04 Oct 2020 12:53:49
User entered 'No (N)'	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-04T08:53:45', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: '220500cc-7dd0-4c95-84d2-88081ad0b35b'	System	04 Oct 2020 12:53:49
User entered '04 Oct 2020 08:53'	System	04 Oct 2020 12:53:49

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 6'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:06', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:08', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:09', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:10', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:12', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered 'None (0)'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:14', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea'	System	05 Oct 2020 09:18:19
User entered 'No (N)'	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T05:18:16', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'f81d1ca0-02f0-464a-a708-628c339eedea' User entered '05 Oct 2020 05:18'	System	05 Oct 2020 09:18:19
	System	05 Oct 2020 09:18:19

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 14:22:08
User entered 'Day 7'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:10', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97'	System	06 Oct 2020 02:35:25
User entered 'None (0)'	System	06 Oct 2020 02:35:25

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:12', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97'	System	06 Oct 2020 02:35:25
User entered 'None (0)'	System	06 Oct 2020 02:35:25

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:13', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97'	System	06 Oct 2020 02:35:25
User entered 'None (0)'	System	06 Oct 2020 02:35:25

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:15', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97'	System	06 Oct 2020 02:35:25
User entered 'None (0)'	System	06 Oct 2020 02:35:25

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:17', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97'	System	06 Oct 2020 02:35:25
User entered 'None (0)'	System	06 Oct 2020 02:35:25

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:19', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97'	System	06 Oct 2020 02:35:25
User entered 'None (0)'	System	06 Oct 2020 02:35:25

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

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 (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:21', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97'	System	06 Oct 2020 02:35:25
User entered 'No (N)'	System	06 Oct 2020 02:35:25

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (066A64B7-39D2-47A1-BF6E-B9B0BC29B2FA)', Time: '2020-10-05T22:35:23', User OID: 'PatientReportedOutcome (US3602111)', ODM File OID: 'a077ed4a-db74-471b-a8d2-864ca3d0cf97'	System	06 Oct 2020 02:35:25
User entered '05 Oct 2020 22:35'	System	06 Oct 2020 02:35:25

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 14:22:08

US3602111

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 14:22:08

US3602111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 12:47:45

US3602111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '6 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 12:47:45

US3602111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	09 Oct 2020 12:47:45

US3602111

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered '8:38 pm and 9:10 pm - Called twice without success. Voice mailbox is full and was unable to leave a message.'	(b) (4), (b) (6)	09 Oct 2020 12:47:45

US3602111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 12:47:50

US3602111

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 12:47:50

US3602111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:23:28

US3602111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 23:23:28

US3602111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	28 Oct 2020 23:23:28

US3602111

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Calls were made on 10/13 and 10/14 no response from subject.'	(b) (4), (b) (6)	28 Oct 2020 23:23:28

US3602111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:23:31

US3602111

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 23:23:31

US3602111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:35:44

US3602111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '20 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 23:35:44

US3602111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	28 Oct 2020 23:35:44

US3602111

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Left voicemail for subject to call back'	(b) (4), (b) (6)	28 Oct 2020 23:35:44

US3602111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:38:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:35:49

US3602111

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:46

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 16:38:35
User entered '1'	System	28 Oct 2020 23:35:49

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:07:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '24 Nov 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '28 Nov 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '01 Dec 2022 00:01'	System	20 Nov 2020 11:07:21

US3602111

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:07:21
Amendment Manager: User entered '05 Dec 2022 23:59'	System	20 Nov 2020 11:07:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:46

[Date of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:20:39
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:11:15
User entered '23 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 23:38:00

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:46

[Time of Contact](#)

Audit	User	Time (GMT)
Comment added 'Time of encounter was 14:29. updated the crf'. DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:22:59
	(b) (4), (b) (6)	10 Nov 2020 21:22:19
User entered '14:29' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:21:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	30 Oct 2020 16:42:47
Query 'Data is required. Please complete.' answered with 'no time noted' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 23:38:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 23:38:00
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 23:38:00

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:46

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 14:29'	System	10 Nov 2020 21:21:19
User entered empty.	System	28 Oct 2020 23:38:00

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:46

[Type of Contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:22:30
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	28 Oct 2020 23:38:00

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:46

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:22:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 23:38:00

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 3 (Day 3)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 1 (Day 1)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 20:02:13
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
User closed query 'Per source, patient presenting with fever, chills, fatigue and positive COVID exposure at work on 23-Oct-2020. Please confirm if subject's symptoms started on 23-Oct-2020 and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 20:43:26
Query 'Per source, patient presenting with fever, chills, fatigue and positive COVID exposure at work on 23-Oct-2020. Please confirm if subject's symptoms started on 23-Oct-2020 and update data accordingly.' answered with 'Subject was exposed to a COVID+ person on 10/23 but on 10/24 started to experience symptoms. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 18:52:08
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:18:47
User opened query 'Per source, patient presenting with fever, chills, fatigue and positive COVID exposure at work on 23-Oct-2020. Please confirm if subject's symptoms started on 23-Oct-2020 and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:18:44
User entered '24 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '26 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:38:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 19:38:47
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:30:59
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered missing code ND - Not Done; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:20:56
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '94' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 23:20:56
User entered empty.	System	10 Nov 2020 23:13:48
User entered '%'	System	05 Nov 2020 19:38:47
User entered empty.	System	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered '99.9' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:40:59
User entered '101' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 23:20:56
User entered '99.9' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:20:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Nov 2020 23:19:36
User entered '99.9' (non-conformant).	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '98.2' F reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:20:51
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 19:38:47
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:30:59

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered '25 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '29 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '99'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 23:26:21
User entered empty.	System	10 Nov 2020 23:13:48
User entered '%'	System	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered '99.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:40:59
User entered '101' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '98.7' F	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:21:41
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:02:13

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '30 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '100'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered '101' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:40:59
User entered '99.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '98' F	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:27:17
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:08:22

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered '27 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '31 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '100'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '98.4' F	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:46:05
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:09:33

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 7 (Day 7)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 5 (Day 5)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered '28 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '30 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '28 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered '0' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:50:51
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 23:13:48
User entered empty.	System	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered '98' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:50:51
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:52:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:59:17
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:52:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:52:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:13:48
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:06:36
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:13:24

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '31 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered '1 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '100'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered '98.7' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.4' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered '98' F	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:52:08
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'Mild (Mild)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:05:06
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:14:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered '30 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '1 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '2 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered '0' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered '100' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 22:12:14
User entered empty.	System	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:23:43
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:41

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change:	(b) (4), (b) (6)	11 Nov 2020 15:38:33
Data Entry Error		
User entered 'Day 10 (Day 10)' reason for change:	(b) (4), (b) (6)	10 Nov 2020 23:19:36
Data Entry Error		
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered '31 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '2 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '3 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	11 Nov 2020 15:38:33
User entered empty.	System	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered '98.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:25:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:15:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change:	(b) (4), (b) (6)	11 Nov 2020 15:38:33
Data Entry Error		
User entered 'Day 11 (Day 11)' reason for change:	(b) (4), (b) (6)	10 Nov 2020 23:19:36
Data Entry Error		
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered '1 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '3 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '4 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered '0' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered '1' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered '100' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '99'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 23:26:21
User entered empty.	System	10 Nov 2020 22:12:14
User entered '%'	System	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.2' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '97.8' F	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:27:25
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)'	(b) (4), (b) (6)	05 Nov 2020 20:16:45

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change:	(b) (4), (b) (6)	11 Nov 2020 15:38:33
Data Entry Error		
User entered 'Day 12 (Day 12)' reason for change:	(b) (4), (b) (6)	10 Nov 2020 23:19:36
Data Entry Error		
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered '2 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '4 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '5 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered '99' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '99' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '100' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	11 Nov 2020 17:42:34
User entered empty.	System	11 Nov 2020 15:38:33
User entered '%'	System	09 Nov 2020 16:24:40
User entered empty.	System	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered '97' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '97.8' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:42:34
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:57
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:39

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)' reason for change:	(b) (4), (b) (6)	11 Nov 2020 15:38:33
Data Entry Error		
User entered 'Day 13 (Day 13)' reason for change:	(b) (4), (b) (6)	10 Nov 2020 23:19:36
Data Entry Error		
User entered 'Day 11 (Day 11)'	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered '3 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '5 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '6 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered '100' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '99' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Nov 2020 16:24:40
User entered empty.	System	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered '98.2' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered '97.4' F reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:32:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:42:10
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:12:14
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:24:40
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:20:51

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)' reason for change:	(b) (4), (b) (6)	11 Nov 2020 15:38:33
Data Entry Error		
User entered 'Day 14 (Day 14)' reason for change:	(b) (4), (b) (6)	10 Nov 2020 23:19:36
Data Entry Error		
User entered 'Day 12 (Day 12)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered '4 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '6 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered '7 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered '100'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered '97.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '97.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered '98.5' F	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:45:21
User entered empty; reason for change New Information	(b) (4), (b) (6)	10 Nov 2020 22:01:53
User entered 'None (None)'	(b) (4), (b) (6)	09 Nov 2020 16:24:40

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Day 14 (Day 14)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 23:19:36
User entered 'Day 13 (Day 13)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered '5 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:39:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 21:39:34
User entered '7 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:24:44
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered '100' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	System	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered '98' F reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '98.5' F reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:39:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:46:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 21:12:45
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	09 Nov 2020 16:41:23
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 16:24:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 14 (Day 14)' reason for change:	(b) (4), (b) (6)	11 Nov 2020 15:38:33
Data Entry Error		
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered '6 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '24 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered '97.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '101' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 23:26:21
User entered '99.9' F	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (14)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:47:30
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:20:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 15 (Day 15)' reason for change:	(b) (4), (b) (6)	11 Nov 2020 15:38:33
Data Entry Error		
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered '7 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered '25 Oct 2020'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered '98.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 17:49:06
User entered '101' F	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 15:38:33
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (15)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 17:50:39
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 23:26:21

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 19 (Day 19)'	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
User entered '8 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (16)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:16

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 20 (Day 20)'	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
User entered '09 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (17)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:30

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 21 (Day 21)'	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (18)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:44

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 22 (Day 22)'	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Date](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (19)

Generated On: 26 Nov 2020 11:09:46

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	20 Nov 2020 14:18:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

[Date of Visit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:42:32
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:42:44
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:10
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 05:42:40
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 'will update accordingly' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 17:21:16
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	03 Nov 2020 17:19:56
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

[Date of Test](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:17
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

[Type of Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:22
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

[Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:27
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:35
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 17:19:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 17:19:56
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:19:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 20:32:26
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:41
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

[CLIA Certified?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:44:44
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 20:32:26

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 11:09:46

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 17:19:56

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

Did the subject have Respiratory Rates $\geq$ 30 per Minute?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Respiratory Rate](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

Did the subject have Heart Rate $\geq$ 125 beats per minute

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Heart Rate](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Oxygen Saturation](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[PaO2](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[ECMO?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Clinical Evidence](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Radiographical Evidence](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Date of Assessment](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[Start Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Covid-19 Assessment 26 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 26 Nov 2020 11:09:46

[End Date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:47:37

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:09:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:09:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 11:09:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:01
User entered '29 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:09:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:09:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 11:09:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:45
User entered '31 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:09:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:09:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 11:09:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:08:49
User entered '2 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:09:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:09:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:15
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 16:29:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 16:29:10
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:29:10
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:40:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 11:09:46

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:07:44
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 21:12:33
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09NOV2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:56:08
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:11:15
User entered '4 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	09 Nov 2020 16:29:10
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:09:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:09:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 21:12:44
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	20 Nov 2020 21:12:44
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:07
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:52:44
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 20:36:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 20:36:38
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 20:36:38
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:40:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 11:09:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 21:12:44
User entered '09 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	20 Nov 2020 21:12:44
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:07
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 17:52:44
User entered '9 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	10 Nov 2020 20:36:38
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:09:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:09:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:00:07
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 19:00:07
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:11
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:52:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 03:47:36
Query 'Data is required. Please complete.' answered with 'date has not occurred yet, will update accordingly.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:37:11
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:40:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 11:09:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:00:07
User entered '16 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 19:00:07
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:11
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:09:46

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:09:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:36:25
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:36:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:52:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 03:47:43
Query 'Data is required. Please complete.' answered with 'date has not occurred yet, will update accordingly.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:37:16
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 19:40:23
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 11:09:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:36:25
User entered '23 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:36:25
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:14:17
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:40:23

US3602111

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:32:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:36:30

US3602111

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:32:05
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:36:30

US3602111

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:32:08
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Nov 2020 19:36:30

US3602111

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	05 Nov 2020 19:36:30

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:27
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:41:37
User closed query 'Per source, vitals time is 0802 (8:02 AM). Please confirm time of vitals and correct accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 20:41:35
Query 'Per source, vitals time is 0802 (8:02 AM). Please confirm time of vitals and correct accordingly.' answered with 'confirmed time with provider. updated' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:04:45
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:40
User entered '8:02' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 15:04:40
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:31
User opened query 'Per source, vitals time is 0802 (8:02 AM). Please confirm time of vitals and correct accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:36:14
User entered '12:17'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '27 Oct 2020 8:02'	System	12 Nov 2020 15:04:40
User entered '27 Oct 2020 12:17'	System	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:20
User entered missing code ND - Not Done.	(b) (4), (b) (6)	05 Nov 2020 19:39:35
DataPoint set to visible.	System	05 Nov 2020 19:36:30

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:22
User entered missing code ND - Not Done.	(b) (4), (b) (6)	05 Nov 2020 19:39:35
DataPoint set to visible.	System	05 Nov 2020 19:36:30

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:37
User entered '98.2' F	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:54
User entered 'Other (Other)'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:33:56
User entered 'Temporal'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:12
User entered '96'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:13
User entered '20'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:14
User entered '100'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:34:16
User entered '73'	(b) (4), (b) (6)	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 19:39:35

US3602111

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:39:45

US3602111

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:36:44
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:39:45

US3602111

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:09:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:37:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:39:52

US3602111

Folder: Illness Visit Day 1 (1)

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

Generated On: 26 Nov 2020 11:09:46

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:37:29
User entered '27 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:39:52

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:46

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '8:35'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '23 Nov 2020 8:35'	System	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '66' in	(b) (4), (b) (6)	23 Nov 2020 14:34:50
DataPoint set to visible.	System	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '164' lb	(b) (4), (b) (6)	23 Nov 2020 14:34:50
DataPoint set to visible.	System	23 Nov 2020 14:33:39

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '58'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '114'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered '69'	(b) (4), (b) (6)	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 14:34:50

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 14:35:07

US3602111

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 14:35:07

US3602111

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:09:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 14:36:10

US3602111

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 26 Nov 2020 11:09:46

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 14:36:10

US3602111

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:46:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 17:22:33

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:50:34
Query 'Sweating was not reported on the source. Please confirm if subject experienced sweating and update data accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:50:27
User opened query 'Sweating was not reported on the source. Please confirm if subject experienced sweating and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:47:23
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Hyperhidrosis, LLT: Sweating - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:43:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:43:41
Data point term sent to Coder	System	10 Nov 2020 23:27:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
Data point term sent to Coder	System	06 Nov 2020 20:26:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Hyperhidrosis, LLT: Sweating - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 17:56:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 17:56:25
Data point term sent to Coder	System	03 Nov 2020 17:40:17
User entered 'Sweating'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:50:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:50:37
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:50:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:50:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '26 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:16
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Nov 2020 16:05:14
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 16:05:14
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Nov 2020 16:05:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:03:30
User closed query 'Per source, start time is 6:00 pm. Please confirm time and enter accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:02:25
Query 'Per source, start time is 6:00 pm. Please confirm time and enter accordingly.' answered with 'update' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:59:29
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'CRA would like a start time listed since it is in the source document. ' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 15:59:25
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Nov 2020 15:55:57
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:57
User entered '18:00' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Nov 2020 15:55:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:52:18
User opened query 'Per source, start time is 6:00 pm. Please confirm time and enter accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:51:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:05:14
User entered '26 Oct 2020 18:00'	System	11 Nov 2020 15:55:57
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	System	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:52:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:46:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:52:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '27 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:46:15
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:19
User closed query 'Per source, stop time is 4:00 pm. Please confirm stop time and enter accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 16:07:45
User closed query 'End time is present for an AE that System did not start within 24 hours after dosing. Please remove the End time.' (Site from System).		11 Nov 2020 16:05:14
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Nov 2020 16:05:14
Query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' answered with 'CRA would like stop time since stop time can be found on source document' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 15:59:54
Query 'Per source, stop time is 4:00 pm. Please confirm stop time and enter accordingly.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:59:33
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	11 Nov 2020 15:58:04
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 15:58:04
User entered '14:00' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Nov 2020 15:58:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:08
User opened query 'Per source, stop time is 4:00 pm. Please confirm stop time and enter accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 15:53:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:05:14
User entered '27 Oct 2020 14:00'	System	11 Nov 2020 15:58:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	System	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:53:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:02
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:09
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:12
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:20
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:46:15
User entered 'Related (RELATED)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

US3602111

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:55:22
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'None (NONE)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	03 Nov 2020 17:46:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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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)	11 Nov 2020 16:09:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 16:09:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	System	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20
User entered '0'	System	03 Nov 2020 17:39:58

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:09:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	10 Nov 2020 23:26:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	06 Nov 2020 20:26:20

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 18:59:49
User entered 'USA-US079-2020-mRNA-1273-P301000003'	System	06 Nov 2020 18:57:38
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 18:57:38

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:38:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:38:56
Data point term sent to Coder	System	23 Nov 2020 14:38:01
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	23 Nov 2020 14:37:47
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 14:37:47
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User entered 'SYMPTOMATIC COVID -19' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:24:13
User closed query 'PV Query: Please update event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:29:22
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)	19 Nov 2020 21:02:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:02:02
Data point term sent to Coder	System	19 Nov 2020 21:01:26
Coding entries removed.	(b) (4), (b) (6)	19 Nov 2020 21:01:22
User entered 'Symptomatic Covid-19' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Nov 2020 21:01:22

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Adverse event](#)

Audit	User	Time (GMT)
Comment added 'Per CCG pg 52, if subject tests positive document at Symptomatic Covid-19'.	(b) (4), (b) (6)	19 Nov 2020 21:00:27
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)	19 Nov 2020 19:23:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	19 Nov 2020 19:23:02
Query 'PV Query: Please update event term to COVID-19.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:07:08
Data point term sent to Coder	System	19 Nov 2020 19:06:58
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:06:43
Coding entries removed.	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User entered 'COVID-19' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User opened query 'PV Query: Please update event term to COVID-19.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:52:04
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
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)	05 Nov 2020 19:45:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	05 Nov 2020 19:45:35
Data point term sent to Coder	System	05 Nov 2020 19:44:23
User entered 'Symptomatic COVID-19'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify event start date; start date should be when the subject began to experience symptoms. The event start date is reported as 30 Oct 2020; however, symptoms were reported on 27 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:29:19
Query 'PV Query: Please clarify event start date; start date should be when the subject began to experience symptoms. The event start date is reported as 30 Oct 2020; however, symptoms were reported on 27 Oct 2020.' answered with 'subject started experiencing symptoms on 10/24/2020' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:09:00
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User entered '24 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User opened query 'PV Query: Please clarify event start date; start date should be when the subject began to experience symptoms. The event start date is reported as 30 Oct 2020; however, symptoms were reported on 27 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:51:02
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '30 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:37:42
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 19:22:02
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 12:47:17
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:37:52
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User entered '02 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4), (b) (6)	06 Nov 2020 20:27:16
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[None](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:02:22
User entered '0' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 22:02:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:02:22
User entered '1' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 22:02:22
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 12:47:20
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:37:57
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	23 Nov 2020 14:37:42
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:50:33
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:29:15
Query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' answered with 'covid exposure documented' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 19:09:35
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User entered 'Subject was exposed to COVID+ patient on 10/23/2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Nov 2020 19:06:43
User opened query 'PV Query: Please confirm if the subject had any known exposure to COVID-19 or risk factors.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 19:51:51
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:47:18
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 19:43:43

US3602111

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:09:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:43:43

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:22:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:32:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:32:43
Data point term sent to Coder	System	29 Sep 2020 14:31:39
Data point term sent to Coder	System	29 Sep 2020 14:25:22
User entered 'Albuterol Inhaler'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Indication](#)

Audit	User	Time (GMT)
User entered 'Asthma'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'puffs'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 14:31:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 14:31:27
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 14:31:27
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 14:24:57
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
User entered 'UN UNK 1993'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 14:24:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:53:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:53:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: MINERALS NOS;VITAMINS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:27:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 14:27:39
Data point term sent to Coder	System	29 Sep 2020 14:26:26
User entered 'Centrum'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'Dietary Supplement'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered '1'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'UN UNK 2018'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:18:06
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 14:26:08

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 17:28:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 17:28:23
Data point term sent to Coder User entered 'Ibuprofen'	System (b) (4), (b) (6)	03 Nov 2020 17:28:00 03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'Fever'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered '1200'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'three times daily (TID)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:24:17
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered empty; reason for change New Information	(b) (4), (b) (6)	11 Nov 2020 16:24:17
User entered 'tid for one day the bid until 10/26 now qday.'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered '24 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 20:11:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User entered '24 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:24:17
User entered '31 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	05 Nov 2020 20:11:18
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:00:58
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM). Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:12:03
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Nov 2020 16:45:05
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 16:44:58
	(b) (4), (b) (6)	06 Nov 2020 13:17:38
	(b) (4), (b) (6)	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 16:24:17
User entered empty.	System	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:24:17
User entered empty.	System	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 16:24:17
User entered empty.	System	03 Nov 2020 17:27:46

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:12:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:12:23
Data point term sent to Coder	System	05 Nov 2020 20:11:41
User entered 'Ibuprofen'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'Headache'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered '1200' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 17:54:57
User entered '800'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered '29 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:28:28
User entered '1 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:28:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User entered '31 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 16:28:28
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:07
User closed query 'Per DM: Was this medication taken for solicited event?' is recorded as "Yes". However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 04:18:27
Query 'Per DM: Was this medication taken for solicited event?' is recorded as "Yes". However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 20:37:46
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	10 Nov 2020 20:37:42
User opened query 'Per DM: Was this medication taken for solicited event?' is recorded as "Yes". However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:26:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 20:11:01

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:55:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:55:33
Data point term sent to Coder	System	11 Nov 2020 16:25:07
User entered 'ibuprofen'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'fever'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered '1200'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered '25 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 19:17:58
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 19:05:03
User entered '28 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	11 Nov 2020 19:05:03
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered '26 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:58:02
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 16:24:52

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:42:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 03:42:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
Data point term sent to Coder	System	11 Nov 2020 16:30:14
User entered 'Ipuprofen'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'Headache'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered '800'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered '1 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered '1 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:05:45
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 16:29:57

US3602111

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 14:26:45

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Visit](#)

Audit	User	Time (GMT)
User entered 'Visit 2 Day 29 (VISIT2)'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Visit Date](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Demographics](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Enrollment](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Medical History Summary](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Medical History](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Vital Signs](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Physical Examination](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Childbearing Potential](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Pregnancy Test](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Randomization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Exposure](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Saliva Collection](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Symptom Log](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[COVID-19 Contact](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Risk of Exposure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Safety Call](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[All](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Study Treatment not given](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Missed Visit](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Missed Assessment](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Visit performed out of window](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Assessment performed out of window](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Clinical site closed](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Travel restrictions](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Exposure to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 26 Nov 2020 11:09:46

[Participant decision](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 16:47:34

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'USA-US079-2020-MRNA-1273-P301000003'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:03
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:09
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Bindu'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:17
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Balani'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:19
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'NJ'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 00:29:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:21
User entered 'US'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 12:47:34
User entered '2'	System	21 Nov 2020 00:29:49
User entered '1'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'USA-US079-2020-MRNA-1273-P301000003'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:03
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:09
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Bindu'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:17
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Balani'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:19
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'NJ'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 00:29:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:21
User entered 'US'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 12:47:34
User entered '2'	System	21 Nov 2020 00:29:49
User entered '1'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '06/Nov/2020 19:00'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:46

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)	21 Nov 2020 00:29:39
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'USA-US079-2020-MRNA-1273-P301000003'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:03
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:09
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Bindu'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:17
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Balani'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:19
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'NJ'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 00:29:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:21
User entered 'US'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 12:47:34
User entered '2'	System	21 Nov 2020 00:29:49
User entered '1'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:09:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '21/Nov/2020 00:29'	System	21 Nov 2020 00:29:49

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 11:09:46

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)	24 Nov 2020 12:47:26
User entered '1'	(b) (4), (b) (6)	21 Nov 2020 00:29:49

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:02
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'USA-US079-2020-MRNA-1273-P301000003'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:03
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:04
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:05
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:07
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:09
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

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Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:10
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:12
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'No (N)'	System	06 Nov 2020 18:57:38

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:13
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Bindu'	System	06 Nov 2020 18:57:38

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:17
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'Balani'	System	06 Nov 2020 18:57:38

US3602111

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[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:19
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:00:21
User entered 'NJ'	System	06 Nov 2020 18:57:38

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Nov 2020 00:29:39
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 15:39:21
User entered 'US'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 12:47:34
User entered '2'	System	21 Nov 2020 00:29:49
User entered '1'	System	06 Nov 2020 19:00:28

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:09:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 07:47'	System	24 Nov 2020 12:47:34

US3602111

Folder: SAE USA-US079-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 11:09:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	24 Nov 2020 12:47:34