

US3602074 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:11:56

All time stamps listed in this document are displayed in GMT

**US3602074**

**Form: Participant Creation**

**Data signed:** (b) (4) 19 Feb 2021 22:11:12

**Generated On: 10 Jun 2021 09:11:56**

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[Participant ID](#)

US3602074

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

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US3602074

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3602074

Folder: Screening

Form: Demographics

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input checked="" type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	True
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

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 22:11:17

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 22:11:17

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 22:11:17

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Condition	POSITIVE PPD (PURIFIED PROTEIN DERIVATIVE) TB TEST (DUE TO BCG VACCINE IN CHILDHOOD)
Start date (dd MMM yyyy)	UN JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 14:12
Height (xxx.x)	66 in
Weight (xxx.x)	165.2 lb
BMI (xxx.x)	26.71973 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:11:17

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 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: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:11:17

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**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 ☐

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**Specify**

SCIENTIST- DATA ANALYTICS -  
NO RISK OF COVID

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** True

**Resides in Nursing Home or Assisted Living Facility** False



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:11:17

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

What was the date of randomization? (dd MMM yyyy) 21 SEP 2020

What was the participant's randomization number? 115010

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**

**Data signed: (b) (4) 19 Feb 2021 22:11:24**

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 14:12
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	16:27 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 16:27
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:11:24

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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: Exposure

Data signed: (b) (4) 19 Feb 2021 22:11:17

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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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 15:50 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 15:50

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

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	14:12 (24 HR)
Collection date and time (derived)	21 SEP 2020 14:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:12	21 SEP 2020 14:12
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

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: 10 Jun 2021 09:11:56

**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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 16:27

PC Open Date & Time

21 SEP 2020 16:10

PC Close Date & Time

21 SEP 2020 18:40

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °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	21 SEP 2020 20:31
PC Open Date & Time	21 SEP 2020 19:35
PC Close Date & Time	22 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:11:56

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 21:24

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:11:56

**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

97.4 °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

23 SEP 2020 21:10

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 19:27

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 20:26

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

26 SEP 2020 20:43

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:11:56

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 14:30

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 16:28

PC Open Date & Time

21 SEP 2020 16:10

PC Close Date & Time

21 SEP 2020 18:40

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

**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

21 SEP 2020 20:32

PC Open Date & Time

21 SEP 2020 19:35

PC Close Date & Time

22 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

**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

22 SEP 2020 21:24

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:11:56

**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

23 SEP 2020 21:10

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:11:56

**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

24 SEP 2020 19:27

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:11:56

**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

25 SEP 2020 20:27

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

**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

26 SEP 2020 20:43

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:11:56

**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

27 SEP 2020 14:31

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

**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 ☐

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 16:29
PC Open Date & Time	21 SEP 2020 16:10
PC Close Date & Time	21 SEP 2020 18:40

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

**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 ☐

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 20:33
PC Open Date & Time	21 SEP 2020 19:35
PC Close Date & Time	22 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:11:56

**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 ☒



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 21:25
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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 ☒

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EAB) (1725)

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**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 21:11
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:11:56

**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 ☒

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EAB) (1725)

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**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 19:28
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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 ☒

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EAB) (1725)

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:27
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 20:43
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 14:31
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3602074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602074

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602074

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3602074

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3602074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 13:37
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3602074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	15:47 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 15:47
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3602074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3602074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

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) 19 OCT 2020

What was the treatment time? (00:00-23:59) 15:17 (24 HR)

Treatment Date and Time (derived) 19 OCT 2020 15:17

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

US3602074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	13:37 (24 HR)
Collection date and time (derived)	19 OCT 2020 13:37

US3602074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Collection date (dd MMM yyyy)			19 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:37	19 OCT 2020 13:37
Nasopharyngeal Swab 2	No		



US3602074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 15:59

PC Open Date & Time

19 OCT 2020 15:37

PC Close Date & Time

19 OCT 2020 18:07

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	19 OCT 2020 20:15
PC Open Date & Time	19 OCT 2020 19:02
PC Close Date & Time	20 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 20:54

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:11:56

**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

97.8 °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

21 OCT 2020 20:56

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 21:13

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 16:57

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 21:30

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59



US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:11:56

**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

97.9 °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

25 OCT 2020 22:22

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 16:00

PC Open Date & Time

19 OCT 2020 15:37

PC Close Date & Time

19 OCT 2020 18:07

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

**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

19 OCT 2020 20:15

PC Open Date & Time

19 OCT 2020 19:02

PC Close Date & Time

20 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

**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

20 OCT 2020 20:54

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:11:56

**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

21 OCT 2020 20:56

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:11:56

**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

22 OCT 2020 21:14

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:11:56

**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

23 OCT 2020 16:57

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

**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

24 OCT 2020 21:31

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59



US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:11:56

**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

25 OCT 2020 22:23

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

**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 ☐

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

No ☒

Yes ☐

PC Time stamp	19 OCT 2020 16:01
PC Open Date & Time	19 OCT 2020 15:37
PC Close Date & Time	19 OCT 2020 18:07

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

**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 ☐

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

No ☒

Yes ☐

PC Time stamp	19 OCT 2020 20:16
PC Open Date & Time	19 OCT 2020 19:02
PC Close Date & Time	20 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:11:56

**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 ☒

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:11:56

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 20:55
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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 ☒



US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:11:56

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 20:57
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:11:56

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 21:14
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:11:56

**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 ☒

PRODUCTION RELEASE (v12.003

95 of 3434

EAB) (1725)

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:11:56

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 16:58
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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 ☒

PRODUCTION RELEASE (v12.003

97 of 3434

EAB) (1725)

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:11:56

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 21:31
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:11:56

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 22:23
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:11:56

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 26 OCT 2020 12:09

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3602074

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:11:56

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 OCT 2020 12:09
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3602074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602074

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602074

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 NOV 2020

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3602074

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3602074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 NOV 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	17 NOV 2020 12:05
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 NOV 2020

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

US3602074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 NOV 2020
Collection time (00:00-23:59)	12:05 (24 HR)
Collection date and time (derived)	17 NOV 2020 12:05

US3602074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:24

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 09:16:22
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 00:01:27
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59



US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 DEC 2020 09:31:00
Patient Cloud Open Date & Time	02 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
116 of 3434	

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

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



Date and time of submission	11 DEC 2020 12:01:30
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	16 DEC 2020 11:41:24
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2020 23:59
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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

01 JAN 2021 11:44:04

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59



US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 20:28:17
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

13 JAN 2021 11:21:35

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 11:12:52
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 09:38:41
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

04 FEB 2021 19:34:38

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

11 FEB 2021 09:30:47

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

17 FEB 2021 09:33:26

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

24 FEB 2021 19:03:20

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59



US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 08:30:01
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

10 MAR 2021 09:38:52

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 13:15:28
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

25 MAR 2021 09:55:46

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

31 MAR 2021 07:41:36

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

08 APR 2021 07:33:01

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

14 APR 2021 07:55:36

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

22 APR 2021 20:22:03

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59



US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

Date and time of submission

28 APR 2021 08:05:50

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 SEP 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59
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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 FEB 2022 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUN 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUL 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUL 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JUL 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

25 SEP 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 OCT 2022 23:59

US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2022 23:59
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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 NOV 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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 ☐



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 NOV 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 NOV 2022 23:59

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US3602074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:11:56

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 NOV 2022 23:59

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US3602074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:11:56

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 15:32:54

US3602074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:06:39

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

SUBJECT WAS ON  
CONVALESCENT PHASE  
DURING THIS TIME. AS PER  
PROTOCOL, NO CONTACT WAS  
MADE WITH SUBJECT FOR  
SCHEDULED SAFETY CALL.

US3602074

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3602074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602074

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:06:39

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

COMBINED WITH OL VISIT DAY

29 ON 02/22/2021

*If Contact Not Made, please provide Comments*

US3602074

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:06:38

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:06:39

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602074

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:06:39

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Apr 2021 01:12:11

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	15 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3602074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Apr 2021 01:12:11

Generated On: 10 Jun 2021 09:11:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 APR 2021
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	15 APR 2021 12:00
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3602074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Apr 2021 01:12:11

Generated On: 10 Jun 2021 09:11:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 APR 2021

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

US3602074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Apr 2021 01:12:11

Generated On: 10 Jun 2021 09:11:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 APR 2021
Collection time (00:00-23:59)	12:18 (24 HR)
Collection date and time (derived)	15 APR 2021 12:18

US3602074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 01:12:11

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3602074**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3602074**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 22:11:13

Generated On: 10 Jun 2021 09:11:56

Date of Contact	29 NOV 2020
Time of Contact	08:15
Date and Time of Contact (derived)	29 NOV 2020 08:15
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input checked="" type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	102.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	3 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	101 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	4 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99 F
-------------	------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	102.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	101 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	100 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 DEC 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Symptom Day

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 22:11:13

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 10 DEC 2020

End Date 10 DEC 2020

Oxygen Saturation 83 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☒ No ☐

Start Date 10 DEC 2020

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

Start Date \_\_\_\_\_



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

**Ventilator Support:**

High-Flow Oxygen?

Yes ☒

No ☐

Start Date

11 DEC 2020

End Date

19 DEC 2020

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

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US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☒  
No ☐

Date of Assessment 10 DEC 2020

Radiographical Evidence Yes ☒  
No ☐

Date of Assessment 10 DEC 2020

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

Start Date

End Date

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Generate Next COVID-19 Assessment**

**Data signed: (b) (4) 19 Feb 2021 22:11:14**

**Generated On: 10 Jun 2021 09:11:56**

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 19 Feb 2021 22:11:15

**Generated On: 10 Jun 2021 09:11:56**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	4 DEC 2020
Day 5	Yes	06 DEC 2020
Day 7	Yes	8 DEC 2020
Day 9	No	
Day 14	No	
Day 21	Yes	23 DEC 2020
Day 28	Yes	30 DEC 2020

US3602074

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:11:15

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3602074

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:11:15

Generated On: 10 Jun 2021 09:11:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 DEC 2020
Time of assessment (00:00-23:59)	12:11 (24 HR)
Vital Signs Date and Time (derived)	2 DEC 2020 12:11
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602074

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:11:15

Generated On: 10 Jun 2021 09:11:56

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.*

US3602074

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 22:11:15

Generated On: 10 Jun 2021 09:11:56

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 DEC 2020



US3602074

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:11:13

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3602074

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:11:13

Generated On: 10 Jun 2021 09:11:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 DEC 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	30 DEC 2020 11:20
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602074

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:11:13

Generated On: 10 Jun 2021 09:11:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 DEC 2020

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

US3602074

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 19 Feb 2021 22:11:13

Generated On: 10 Jun 2021 09:11:56

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 DEC 2020

US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	18 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:06:38

Generated On: 10 Jun 2021 09:11:56

Date of updated informed consent ( <i>dd MMM yyyy</i> )	18 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	18 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 12:30
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG



US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 13:30
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 18 JAN 2021

What was the treatment time? (00:00-23:59) 13:00 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 13:00

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

US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	18 JAN 2021
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Collection time (00:00-23:59)	12:30 (24 HR)
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Collection date and time (derived)	18 JAN 2021 12:30
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US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	12:28
Collection Date and Time (derived)	18 JAN 2021 12:28

US3602074

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602074

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:17

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1



US3602074

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3602074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 13:40
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3602074

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:11:16

Generated On: 10 Jun 2021 09:11:56

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 15:00
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3602074

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:11:15

Generated On: 10 Jun 2021 09:11:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3602074

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:11:15

Generated On: 10 Jun 2021 09:11:56

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 FEB 2021

What was the treatment time? (00:00-23:59) 14:25 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 14:25

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

US3602074

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:11:15

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602074

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:06:39

Generated On: 10 Jun 2021 09:11:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602074

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:06:39

Generated On: 10 Jun 2021 09:11:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3602074

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3602074

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:06:38

Generated On: 10 Jun 2021 09:11:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 MAR 2021
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 10:35
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL/FOREHEAD SCANNER WAS USED
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602074

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 MAR 2021

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

US3602074

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 MAR 2021
Collection time (00:00-23:59)	10:55 (24 HR)
Collection date and time (derived)	12 MAR 2021 10:55

US3602074

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 22:11:12

Generated On: 10 Jun 2021 09:11:56

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

AEID	USA-US079-2020-MRNA-1273-P30 1000007
Adverse event	SYMPTOMATIC COVID - 19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	29 NOV 2020
Start time (00:00-23:59)	19:00 (24 HR)
AE start date and time (derived)	29 NOV 2020 19:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	20 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

Number of Days in ICU	
Persistent or significant disability or incapacity	True
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	RECOVERING WITH SEQUELAE WITH RESTING TACHYCARDIA AND EXERTIONAL DYSPNEA AND REQUIRING NASAL OXYGEN SUPPLEMENTATION

Narrative

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

---

PT WITH SEVERE HYPOXEMIA  
AT HOME AND COUGH AND  
CHEST PAIN AND THUS WENT  
TO THE ED AND IS CURRENTLY  
ADMITTED WITH NEED FOR  
OXYGEN SUPPLEMENTATION  
AND MEDICATIONS FOR THE  
SAME . PT STARTED ON  
ANTIBIOTICS , REMDESEVIR  
AND STEROIDS .

PT SINCE THE LAST VISIT HAD  
VISITED THE ER ON 12/8 AND  
DCED HOME WITHOUT ANY  
INVESTIGATIONS BEING DONE  
DUE TO PULSE OF OF > 95% ON  
ROOM AIR  
HE WENT BACK TO THE  
HOSPITAL ON 12/10 DUE TO SIG  
HYPOXEMIA AND CHEST WALL  
PAIN AND PLEURISY  
ASSOCIATED WITH COUGH  
AND WAS THEN ADMITTED  
FOR 10D AND DCED ON 12/20/20  
. THE HAD RESP FAILURE WITH  
NADIR OXYGEN ON ROOM AIR  
OF 85 % . PT RECEIVED  
STEROIDS , REMDESIVIR AND  
OXYGEN SUPPLEMENTATION.  
HE WAS DCED ON 2 LIT NASAL  
CANULA SINCE WAS SON ON  
WALKING ( EXERTIONAL  
DYSPNEA) AND WITH RESTING  
TACHYCARDIA ( BASELINE  
PRIOR TO ILLNESS



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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

~ 80S AND NOW IN THE MID  
90S).

COUGH IS IMPROVING BUT  
STILL ONGOING AND TAKING  
PHENARGAN SYRUP PRN FOR  
THE SAME . HE WAS PLACED  
ON ANTICOAGULATION IN  
HOSPITAL AND WAS DCED ON  
BABY ASA 81 MG PO DAILY .  
HE IS TAKING VIT D 2000U , VIT  
C 1000MG AND ZINCE 100MG PO  
DAILY  
NO OTHER VITAMINS OR  
SUPPLEMENTS TAKEN

3 KIDS ( 2 MILDLY  
SYMPTOMATIC AND ONE  
ASYMPTOMATIC ) AT HOME  
ALSO WERE POSITIVE FOR  
COVID THE SAME TIME AND  
HAVE SINCE RECOVERED .  
WIFE TESTED MULTIPLE TIMES  
WAS NEGATIVE

ROS : NO BILATERAL KNEE  
PAIN OR MYALGIAS ( BOTH  
ENDED 3D INTO HOSPITAL  
STAY : 12/13/20 )

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3602074

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

AEID

Adverse event

BILATERAL KNEE PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 DEC 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 (2)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

AEID

Adverse event

LIGHTHEADEDNESS

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)

5 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

5 DEC 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 (3)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 22:11:13

Generated On: 10 Jun 2021 09:11:56

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

Yes ☒

No ☐

---

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

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US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication LEUTIN EYE DROPS

Prophylaxis Yes ☐  
No ☒

Indication FOR EYE STRENGTH  
PREVENTATIVE

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☐  
No ☒

Indication PREVENTIVE HEALTH

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ALEVE (NAPROXEN) (DOSAGE: UNKNOWN)

Prophylaxis Yes ☐  
No ☒

Indication SLIGHT HEADACHE

Dose per administration 2

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication FEVER - LISTED ON SYMPTOM  
TRACKER LOG

Dose per administration 500

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		2 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ALEVE (NAPROXEN)

Prophylaxis Yes ☐  
No ☒

Indication FEVER - LISTED ON SYMPTOM  
TRACKER LOG

Dose per administration 440

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	2 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ZITHROMAX AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication SORE THROAT - LISTED ON  
SYMPTOM TRACKER LOG

Dose per administration 500

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ZITHROMAX AZITHROMYCIN

Prophylaxis Yes ☐  
No ☒

Indication SORE THROAT - LISTED ON  
SYMPTOM TRACKER LOG

Dose per administration 250

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	5 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ALEVE

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE - LISTED IN  
SYMPTON TRACKER LOG

Dose per administration 220

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	3 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	6 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 21:05:30

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Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication DIETARY/NUTRITIONAL  
SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 21:05:30

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Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication DIETARY/NUTRITIONAL  
SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ZINC

Prophylaxis Yes ☒  
No ☐

Indication DIETARY/NUTRITIONAL  
SUPPLEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		3 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ALBUTEROL HFA (PROVENTIL,  
VENTOLIN, PROAIR) 108 (90  
BASE) MCG/ACT INHALER

Prophylaxis Yes ☐  
No ☒

Indication SPASM OF LUNG AIR PASSAGES  
AND WHEEZING

Dose per administration 2

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

EVERY 6 HOURS AS NEEDED  
FOR WHEEZING FOR UP TO 14  
DAYS

Route of administration Oral ☐

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Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 21:05:30

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	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		8 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication BENZONATATE (TESSALON)

Prophylaxis Yes ☐  
No ☒

Indication COUGH

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 21:05:30

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Name of Medication ASPRIN

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF CLOTS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication PHENERGAN

Prophylaxis Yes ☐  
No ☒

Indication COUGH SUPPRESSANT -  
CAPTURED IN ILLNESS VISIT

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 9

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

If dose unit is Other, specify

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

If frequency is Other, specify

NIGHTLY

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication DEXAMETHASONE PF  
(DECADRON PF)

Prophylaxis Yes ☐  
No ☒

Indication COVID

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 24  
HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication POLYETHYLENE GLYCOL  
(MIRALAX) PACKET 17 G

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 17

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication DOCUSATE (COLACE) LIQUID

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

2 TIMES  
DAILY PRN

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ENOXAPARIN (LOVENOX)

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF  
BLOOD CLOTS

Dose per administration 40

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

EVERY 12  
HOURS  
SCHEDULED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication VANCOMYCIN 1.5 G IN NS  
500 ML IVPB (PREMIX)

Prophylaxis Yes ☐  
No ☒

Indication BACTEREMIA

Dose per administration 1.5/500

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

If dose unit is Other, specify G/ML

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

If frequency is Other, specify EVERY 12  
HOURS  
INTERVAL

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication LOPERAMIDE (IMODIUM)

Prophylaxis Yes ☐  
No ☒

Indication DIARRHEA

Dose per administration 2

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

EVERY 6  
HOURS PRN

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication VANCOMYCIN  
(VANCOCIN) 1 G IN 200  
ML NS (FROZEN  
PREMIX)

Prophylaxis Yes ☐  
No ☒

Indication BACTEREMIA

Dose per administration 1/200

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

If dose unit is Other, specify G/ML

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

If frequency is Other, specify EVERY 12  
HOURS  
INTERVAL

Route of administration Oral ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 3

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

NIGHTLY

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication TRAMADOL (ULTRAM)

Prophylaxis Yes ☐  
No ☒

Indication PAIN RELIEF

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8  
HOURS PRN

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication DEXAMETHASONE PF  
(DECADRON PF)

Prophylaxis Yes ☐  
No ☒

Indication COVID

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12  
HOURS  
SCHEDULED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication	REMDESIVIR (VEKLURY) 200 MG IN NS 250 ML
--------------------	---

Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
-------------	--

Indication	COVID
------------	-------

Dose per administration	200/250
-------------------------	---------

Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
-----------	--

If dose unit is Other, specify	MG/ML
--------------------------------	-------

Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
-----------	--

If frequency is Other, specify	
--------------------------------	--

Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>
-------------------------	--

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication	REMDESIVIR (VEKLURY) 100 MG IN NS 250 ML
--------------------	---

Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
-------------	--

Indication	COVID
------------	-------

Dose per administration	100/250
-------------------------	---------

Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
-----------	--

If dose unit is Other, specify	MG/ML
--------------------------------	-------

Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
-----------	--

If frequency is Other, specify	
--------------------------------	--

Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>
-------------------------	--

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	14 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication DEXAMETHASONE PF  
(DECADRON PF)

Prophylaxis Yes ☐  
No ☒

Indication COVID

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication DEXAMETHASONE PF  
(DECADRON PF)

Prophylaxis Yes ☐  
No ☒

Indication COVID

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 24  
HOURS  
SCHEDULED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication FAMOTIDINE (PEPCID)  
TABLET 20 MG

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ALBUTEROL HFA  
(PROVENTIL,  
VENTOLIN, PROAIR)  
INHALER (NON-VENTED)

Prophylaxis Yes ☐  
No ☒

Indication DYSPNEA

Dose per administration 2

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

EVERY 6  
HOURS PRN

Route of administration Oral ☐  
Topical ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
<hr/>		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication BENZONATATE  
(TESSALON)

Prophylaxis Yes ☐  
No ☒

Indication COUGH

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication	PROMETHAZINE-CODEINE (PHENERGAN WITH CODEINE) 6.25-10 MG/5ML SYRUP 5 ML
--------------------	--

Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
-------------	--

Indication	COUGH
------------	-------

Dose per administration	6.25-10/5
-------------------------	-----------

Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
-----------	---

If dose unit is Other, specify	MG/ML
--------------------------------	-------

Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
-----------	---

If frequency is Other, specify	EVERY 4 HOURS PRN
--------------------------------	----------------------

Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/>
-------------------------	--

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
<hr/>		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ACETAMINOPHEN  
(TYLENOL)

Prophylaxis Yes ☐  
No ☒

Indication FEVER RELIEF

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6  
HOURS PRN

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication ENOXAPARIN (LOVENOX)

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF  
CLOTS

Dose per administration 40

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

EVERY 24  
HOURS  
SCHEDULED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication CEFTRIAXONE  
(ROCEPHIN)

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

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

EVERY 24  
HOURS  
INTERVAL

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication AZITHROMYCIN  
(ZITHROMAX)

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 500/250

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

If dose unit is Other, specify MG/ML

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication LOW GRADE FEVER OF 99.2 -  
CAPTURED IN EDIARY THE  
DAY AFTER IP WAS  
ADMINISTERED

Dose per administration 500

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 JAN 2021	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Name of Medication	OXYGEN SUPPLEMENTATION
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	DUE TO COVID-19 (WHILE BEING HOSPITALIZED)
Dose per administration	UNK
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input checked="" type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3602074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 22:11:13

Generated On: 10 Jun 2021 09:11:56

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3602074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 21:05:30

Generated On: 10 Jun 2021 09:11:56

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 DEC 2020	CHEST X-RAY	Adverse Event	
14 DEC 2020	CHEST X-RAY	Adverse Event	
20 DEC 2020	CHEST X-RAY	Adverse Event	



US3602074

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:11:56

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

US3602074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:11:56

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 ☐

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	14/DEC/2020 06:58
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

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	18/DEC/2020 17:07
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

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	21/DEC/2020 14:06
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

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	29/DEC/2020 10:53
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

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	04/JAN/2021 15:15
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



US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	05/JAN/2021 09:14
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

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	05/JAN/2021 10:21
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

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (8)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	06/JAN/2021 10:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (9)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	07/JAN/2021 08:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (10)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	12/JAN/2021 14:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (11)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	20/JAN/2021 19:56
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

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (12)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	11/FEB/2021 09:57
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

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (13)

Data signed: (b) (4) 27 Apr 2021 03:56:49

Generated On: 10 Jun 2021 09:11:56

SAEID	USA-US079-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	13
Date of submission (Pre-filled from custom function)	26/APR/2021 12:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3602074 (Prod: Hackensack University Medical Center)

**US3602074**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:11:56**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:00:04
User entered 'US3602074'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 18:01:09

**US3602074**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:24:52

**US3602074**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '21 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 18:01:10

**US3602074**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:24:52

**US3602074**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'SCRN'	System	21 Sep 2020 19:24:52

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 18:01:11

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '50'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03



**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'YEARS'	System	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered '50'	System	21 Sep 2020 19:26:17

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:57:36
User entered '1' reason for change: New Information	(b) (4), (b) (6)	20 Apr 2021 17:57:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03



**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

US3602074

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:11:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
User closed query 'Per CDM: "Other" has been selected for Race, however, please review the predefined options and update if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 07:15:40
Query 'Per CDM: "Other" has been selected for Race, however, please review the predefined options and update if appropriate.' answered with 'Data updated per query.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 17:59:42
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 17:57:36
User entered '0' reason for change: New Information	(b) (4), (b) (6)	20 Apr 2021 17:57:36
User opened query 'Per CDM: "Other" has been selected for Race, however, please review the predefined options and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 13:19:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:57:36
User entered empty; reason for change New Information	(b) (4), (b) (6)	20 Apr 2021 17:57:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Unknown'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:11:56**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:03

**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:17

**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'Sep 2020'	System	21 Sep 2020 19:26:17

**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered '2020'	System	21 Sep 2020 19:26:17



**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 19:26:30
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:26:30
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 19:26:17
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:26:17

**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:17

**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:17

**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:17

**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:17

**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 18:01:10

**US3602074**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:11:56**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'I'	System	21 Sep 2020 19:26:40

**US3602074**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:26:40



**US3602074**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:11:56**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:28:40

US3602074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please specify the diagnosis/medical condition as opposed to the LABORATORY ABNORMALITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 05:03:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Oct 2020 22:16:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Oct 2020 22:16:39
Data point term sent to Coder	System	25 Oct 2020 22:15:40
Query 'Per DM CLR: Please specify the diagnosis/medical condition as opposed to the LABORATORY ABNORMALITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Vitamin D Deficiency ' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 22:14:58
Coding entries removed.	(b) (4), (b) (6)	25 Oct 2020 22:14:53
User entered 'Vitamin D Deficiency' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Oct 2020 22:14:53
User opened query 'Per DM CLR: Please specify the diagnosis/medical condition as opposed to the LABORATORY ABNORMALITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 14:38:41

US3602074

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:11:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Metabolic, nutritional and blood gas investigations, HLT: Vitamin analyses, PT: Vitamin D decreased, LLT: Vitamin D low - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 19:29:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 19:29:46
Data point term sent to Coder	System	21 Sep 2020 19:29:13
User entered 'Low Vit D'	(b) (4), (b) (6)	21 Sep 2020 19:29:08

**US3602074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:08

**US3602074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:08

**US3602074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:08

**US3602074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:08

**US3602074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:08



**US3602074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered empty.	System	21 Sep 2020 19:29:08

**US3602074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered empty.	System	21 Sep 2020 19:29:08

**US3602074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered empty.	System	21 Sep 2020 19:29:08

**US3602074**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered empty.	System	21 Sep 2020 19:29:08

US3602074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Mycobacteria identification and serology, PT: Tuberculin test positive, LLT: PPD skin test positive - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 12:06:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 12:06:55
Data point term sent to Coder	System	06 Nov 2020 03:56:34
User entered 'Positive PPD (PURIFIED PROTEIN DERIVATIVE) TB test (due to BCG Vaccine in childhood)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 03:55:37
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.	(b) (4), (b) (6)	28 Oct 2020 05:04:18
' (Site from DM).		
Data point term sent to Coder	System	25 Oct 2020 22:16:41
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.	(b) (4), (b) (6)	25 Oct 2020 22:15:50
' answered with 'HISTORY OF PURIFIED PROTEIN DERIVATIVE' (Site from DM).		
User entered 'HISTORY OF purified protein derivative' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Oct 2020 22:15:42
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.	(b) (4), (b) (6)	21 Oct 2020 14:39:08
' (Site from DM).		
Data point term sent to Coder	System	05 Oct 2020 17:47:35
User closed query 'CDM-Coding: Please expand/spell out the reported abbreviation OD PPC and provide the full text.' (Site from System).	System	05 Oct 2020 17:47:07
Query 'CDM-Coding: Please expand/spell out the reported abbreviation OD PPC and provide the full text.' answered with 'OF PPD POSITIVE' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 17:47:07

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:56

[Condition](#)

Audit	User	Time (GMT)
User entered 'HISTORY OF PPD POSITIVE'	(b) (4), (b) (6)	05 Oct 2020 17:46:52
reason for change: Data Entry Error		
User opened query 'CDM-Coding: Please	Coder Import (b) (4)	29 Sep 2020 08:16:44
expand/spell out the reported abbreviation OD PPC	(b) (4)	
and provide the full text. ' (Site from System).		
Data point term sent to Coder	System	21 Sep 2020 19:30:15
User entered 'HX od ppc positive'	(b) (4), (b) (6)	21 Sep 2020 19:29:41

**US3602074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'UN Jul 2020' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 03:55:37
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:29:41

**US3602074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0' reason for change: New Information	(b) (4) (b) (4), (b) (6)	06 Nov 2020 03:55:37
User entered '1'	(b) (4), (b) (6)	21 Sep 2020 19:29:41



US3602074

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:11:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and confirm if this medical condition is active/ongoing. Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:55:04
Query 'Per DM CLR: Please review and confirm if this medical condition is active/ongoing. Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	06 Nov 2020 03:56:31
' answered with 'Subject received positive PPD TB test result due to ongoing immunity due to BCG vaccination in childhood.' (Site from DM).		
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	06 Nov 2020 03:56:24
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	06 Nov 2020 03:55:37
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	06 Nov 2020 03:55:37
User opened query 'Per DM CLR: Please review and confirm if this medical condition is active/ongoing. Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:43:07

**US3602074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	21 Sep 2020 19:29:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:29:58
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	21 Sep 2020 19:29:41
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 19:29:41

**US3602074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'UN Jul 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	06 Nov 2020 03:56:24
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:29:41

**US3602074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:29:41

**US3602074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'Jul 2020'	System	06 Nov 2020 03:55:37
User entered empty.	System	21 Sep 2020 19:29:41

**US3602074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered '2020'	System	06 Nov 2020 03:55:37
User entered empty.	System	21 Sep 2020 19:29:41

**US3602074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'Jul 2020'	System	06 Nov 2020 03:56:24
User entered empty.	System	21 Sep 2020 19:29:41

**US3602074**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered '2020'	System	06 Nov 2020 03:56:24
User entered empty.	System	21 Sep 2020 19:29:41



**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '14:12'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 19:32:42

US3602074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Sep 2020 19:44:54
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:44:54
User entered '66' in reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:44:54
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:32:42
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:32:42
DataPoint set to visible.	System	21 Sep 2020 19:26:40

US3602074

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:56

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	21 Sep 2020 19:44:54
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:44:54
User entered '165.2' lb reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:44:54
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:32:42
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:32:42
DataPoint set to visible.	System	21 Sep 2020 19:26:40

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered '26.71973'	System	21 Sep 2020 19:44:54
User entered empty.	System	21 Sep 2020 19:32:42
DataPoint set to visible.	System	21 Sep 2020 19:26:40

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'kg/m2'	System	21 Sep 2020 19:44:54
User entered empty.	System	21 Sep 2020 19:32:42
DataPoint set to visible.	System	21 Sep 2020 19:26:40



**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'bpm'	System	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'breaths/min'	System	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42



**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'mmHg'	System	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User entered 'mmHg'	System	21 Sep 2020 19:32:42

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47

**US3602074**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47

**US3602074**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:33:10

**US3602074**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:33:10

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18



**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

US3602074

Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

US3602074

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

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**Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

US3602074

Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

US3602074

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

US3602074

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18



US3602074

Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

US3602074

Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

**[Specify](#)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'scientist- data analytics - no risk of covid'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

**Resides in Nursing Home or Assisted Living Facility**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18



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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:19:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:34:18

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:39:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:39:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:39:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'VISIT1'	System	21 Sep 2020 19:39:45



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '21 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 18:30:49

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '115010'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 18:30:49

US3602074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 18:30:49

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:40:25

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:40:25

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:40:25

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:40:25

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:11:56**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:40:25



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:40:25
DataPoint set to visible.	System	21 Sep 2020 19:26:30

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '14:12'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '82'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'bpm'	System	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '18'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'breaths/min'	System	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '133'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '82'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:43:28

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 20:40:45



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '16:27'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '21 Sep 2020 16:27'	System	21 Sep 2020 20:40:45

US3602074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:11:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 10:08:00
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	(b) (4), (b) (6)	21 Sep 2020 20:44:07
answered with 'NCS' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Sep 2020 20:40:45
User entered '96.6' F	(b) (4), (b) (6)	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '74'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:40:45



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'bpm'	System	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '18'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'breaths/min'	System	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '120'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '76'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	21 Sep 2020 20:40:45

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:19



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:19

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:53:46

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:53:46

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:53:46

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:53:46

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '15:50'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:53:46

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '21 Sep 2020 15:50'	System	21 Sep 2020 19:53:46



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:53:46

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'ONCE'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:36

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:36

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '14:12'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:36

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 19:45:36

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:11:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:51



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 19:45:51

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:51

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '14:12'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:51

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 19:45:51

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 19:45:51

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:51

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:51

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered empty.	System	21 Sep 2020 19:45:51



**US3602074**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 19:45:56

**US3602074**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	21 Sep 2020 19:45:56

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:27:08', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '297d706f-4fd8-44f9-ae4e-03d36ab817d5'	System	21 Sep 2020 20:27:30
User entered 'Yes (Y)'	System	21 Sep 2020 20:27:30

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:27:15', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '297d706f-4fd8-44f9-ae4e-03d36ab817d5' User entered '96.6'	System	21 Sep 2020 20:27:30
	System	21 Sep 2020 20:27:30

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:27:22', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '297d706f-4fd8-44f9-ae4e-03d36ab817d5'	System	21 Sep 2020 20:27:30
User entered 'No (N)'	System	21 Sep 2020 20:27:30

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:27:26', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '297d706f-4fd8-44f9-ae4e-03d36ab817d5'	System	21 Sep 2020 20:27:30
User entered '21 Sep 2020 16:27'	System	21 Sep 2020 20:27:30

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Sep 2020 16:10'	System	21 Sep 2020 19:53:46



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Sep 2020 18:40'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:31:38', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '45dc26ef-9adc-4fe7-b079-81dace54637b' User entered 'Yes (Y)'	System	22 Sep 2020 00:31:59
	System	22 Sep 2020 00:31:59

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:31:44', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '45dc26ef-9adc-4fe7-b079-81dace54637b' User entered '97.9'	System	22 Sep 2020 00:31:59
	System	22 Sep 2020 00:31:59

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:31:50', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '45dc26ef-9adc-4fe7-b079-81dace54637b' User entered 'No (N)'	System	22 Sep 2020 00:31:59
	System	22 Sep 2020 00:31:59

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:31:54', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '45dc26ef-9adc-4fe7-b079-81dace54637b' User entered '21 Sep 2020 20:31'	System	22 Sep 2020 00:31:59
	System	22 Sep 2020 00:31:59

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Sep 2020 19:35'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 19:53:46



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 2'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:23:52', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f462fc21-da34-4dbe-8756-8dda47a59ba9' User entered 'Yes (Y)'	System	23 Sep 2020 01:24:17
	System	23 Sep 2020 01:24:17

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f462fc21-da34-4dbe-8756-8dda47a59ba9' User entered '97.1'	System	23 Sep 2020 01:24:17
	System	23 Sep 2020 01:24:17

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:08', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f462fc21-da34-4dbe-8756-8dda47a59ba9'	System	23 Sep 2020 01:24:17
User entered 'No (N)'	System	23 Sep 2020 01:24:17

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f462fc21-da34-4dbe-8756-8dda47a59ba9' User entered '22 Sep 2020 21:24'	System	23 Sep 2020 01:24:17
	System	23 Sep 2020 01:24:17

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 3'	System	21 Sep 2020 19:53:46



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:07', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '18b270d0-5c76-4fbb-bd67-6feb6089f649'	System	24 Sep 2020 01:10:28
User entered 'Yes (Y)'	System	24 Sep 2020 01:10:28

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:12', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '18b270d0-5c76-4fbb-bd67-6feb6089f649' User entered '97.4'	System	24 Sep 2020 01:10:28
	System	24 Sep 2020 01:10:28

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:20', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '18b270d0-5c76-4fbb-bd67-6feb6089f649'	System	24 Sep 2020 01:10:28
User entered 'No (N)'	System	24 Sep 2020 01:10:28

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:25', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '18b270d0-5c76-4fbb-bd67-6feb6089f649'	System	24 Sep 2020 01:10:28
User entered '23 Sep 2020 21:10'	System	24 Sep 2020 01:10:28

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 4'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:26:47', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '52f3745b-6fe8-4482-8bdc-3f6a1ca189f3' User entered 'Yes (Y)'	System	24 Sep 2020 23:27:04
	System	24 Sep 2020 23:27:04



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:26:53', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '52f3745b-6fe8-4482-8bdc-3f6a1ca189f3' User entered '97.6'	System	24 Sep 2020 23:27:04
	System	24 Sep 2020 23:27:04

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:26:58', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '52f3745b-6fe8-4482-8bdc-3f6a1ca189f3'	System	24 Sep 2020 23:27:04
User entered 'No (N)'	System	24 Sep 2020 23:27:04

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:01', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '52f3745b-6fe8-4482-8bdc-3f6a1ca189f3' User entered '24 Sep 2020 19:27'	System	24 Sep 2020 23:27:04
	System	24 Sep 2020 23:27:04

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 5'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:26:35', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '28029c1f-1453-42dd-85d0-1948cb9868ee' User entered 'Yes (Y)'	System	26 Sep 2020 00:26:54
	System	26 Sep 2020 00:26:54

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:26:41', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '28029c1f-1453-42dd-85d0-1948cb9868ee' User entered '97.6'	System	26 Sep 2020 00:26:54
	System	26 Sep 2020 00:26:54



US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:26:17', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '28029c1f-1453-42dd-85d0-1948cb9868ee' User entered 'No (N)'	System	26 Sep 2020 00:26:54
	System	26 Sep 2020 00:26:54

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:26:51', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '28029c1f-1453-42dd-85d0-1948cb9868ee' User entered '25 Sep 2020 20:26'	System	26 Sep 2020 00:26:54
	System	26 Sep 2020 00:26:54

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 6'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:42:46', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'c4b9accf-cbc2-48e2-91b1-1948866e48ab' User entered 'Yes (Y)'	System	27 Sep 2020 00:43:09
	System	27 Sep 2020 00:43:09

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:42:50', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'c4b9accf-cbc2-48e2-91b1-1948866e48ab' User entered '97.7'	System	27 Sep 2020 00:43:09
	System	27 Sep 2020 00:43:09

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:42:59', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'c4b9accf-cbc2-48e2-91b1-1948866e48ab' User entered 'No (N)'	System	27 Sep 2020 00:43:09
	System	27 Sep 2020 00:43:09



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:05', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'c4b9accf-cbc2-48e2-91b1-1948866e48ab' User entered '26 Sep 2020 20:43'	System	27 Sep 2020 00:43:09
	System	27 Sep 2020 00:43:09

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 7'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:30:28', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '24005a29-31c8-4954-94bb-ff8ee58c2f9f' User entered 'Yes (Y)'	System	27 Sep 2020 18:30:43
	System	27 Sep 2020 18:30:43

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:30:33', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '24005a29-31c8-4954-94bb-ff8ee58c2f9f' User entered '97.6'	System	27 Sep 2020 18:30:43
	System	27 Sep 2020 18:30:43

US3602074

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:30:36', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '24005a29-31c8-4954-94bb-ff8ee58c2f9f' User entered 'No (N)'	System	27 Sep 2020 18:30:43
	System	27 Sep 2020 18:30:43

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:30:39', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '24005a29-31c8-4954-94bb-ff8ee58c2f9f' User entered '27 Sep 2020 14:30'	System	27 Sep 2020 18:30:43
	System	27 Sep 2020 18:30:43



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 19:53:46

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:28:02', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '1b08a7af-1a2a-4c94-8e27-fd9a9f907261'	System	21 Sep 2020 20:29:05
User entered 'None (1)'	System	21 Sep 2020 20:29:05

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:28:40', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '1b08a7af-1a2a-4c94-8e27-fd9a9f907261' User entered 'No (N)'	System	21 Sep 2020 20:29:05
	System	21 Sep 2020 20:29:05

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:28:44', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '1b08a7af-1a2a-4c94-8e27-fd9a9f907261' User entered 'No (N)'	System	21 Sep 2020 20:29:05
	System	21 Sep 2020 20:29:05

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:28:54', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '1b08a7af-1a2a-4c94-8e27-fd9a9f907261'	System	21 Sep 2020 20:29:05
User entered 'None (1)'	System	21 Sep 2020 20:29:05

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:28:57', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '1b08a7af-1a2a-4c94-8e27-fd9a9f907261' User entered '21 Sep 2020 16:28'	System	21 Sep 2020 20:29:05
	System	21 Sep 2020 20:29:05



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Sep 2020 16:10'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Sep 2020 18:40'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 19:53:46

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:32:11', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66bd5076-3968-40e3-8637-428efa516ecd' User entered 'None (1)'	System	22 Sep 2020 00:32:44
	System	22 Sep 2020 00:32:44

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:32:19', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66bd5076-3968-40e3-8637-428efa516ecd' User entered 'No (N)'	System	22 Sep 2020 00:32:44
	System	22 Sep 2020 00:32:44

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:32:28', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66bd5076-3968-40e3-8637-428efa516ecd' User entered 'No (N)'	System	22 Sep 2020 00:32:44
	System	22 Sep 2020 00:32:44

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:32:38', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66bd5076-3968-40e3-8637-428efa516ecd' User entered 'None (1)'	System	22 Sep 2020 00:32:44
	System	22 Sep 2020 00:32:44

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:32:41', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66bd5076-3968-40e3-8637-428efa516ecd' User entered '21 Sep 2020 20:32'	System	22 Sep 2020 00:32:44
	System	22 Sep 2020 00:32:44



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Sep 2020 19:35'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 2'	System	21 Sep 2020 19:53:46

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:19', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '16e68ff0-eb5c-4114-95e8-acddfa02ee77'	System	23 Sep 2020 01:24:44
User entered 'None (1)'	System	23 Sep 2020 01:24:44

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:24', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '16e68ff0-eb5c-4114-95e8-acddfa02ee77' User entered 'No (N)'	System	23 Sep 2020 01:24:44
	System	23 Sep 2020 01:24:44

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:27', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '16e68ff0-eb5c-4114-95e8-acddfa02ee77'	System	23 Sep 2020 01:24:44
User entered 'No (N)'	System	23 Sep 2020 01:24:44

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:39', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '16e68ff0-eb5c-4114-95e8-acddfa02ee77'	System	23 Sep 2020 01:24:44
User entered 'None (1)'	System	23 Sep 2020 01:24:44

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:43', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '16e68ff0-eb5c-4114-95e8-acddfa02ee77' User entered '22 Sep 2020 21:24'	System	23 Sep 2020 01:24:44
	System	23 Sep 2020 01:24:44



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 3'	System	21 Sep 2020 19:53:46

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:32', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4cea779c-b68a-4951-8cf2-4eff3768e6af' User entered 'None (1)'	System	24 Sep 2020 01:10:50
	System	24 Sep 2020 01:10:50

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:11:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:35', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4cea779c-b68a-4951-8cf2-4eff3768e6af' User entered 'No (N)'	System	24 Sep 2020 01:10:50
	System	24 Sep 2020 01:10:50

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:43', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4cea779c-b68a-4951-8cf2-4eff3768e6af' User entered 'No (N)'	System	24 Sep 2020 01:10:50
	System	24 Sep 2020 01:10:50

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:46', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4cea779c-b68a-4951-8cf2-4eff3768e6af' User entered 'None (1)'	System	24 Sep 2020 01:10:50
	System	24 Sep 2020 01:10:50

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:48', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4cea779c-b68a-4951-8cf2-4eff3768e6af' User entered '23 Sep 2020 21:10'	System	24 Sep 2020 01:10:50
	System	24 Sep 2020 01:10:50



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 4'	System	21 Sep 2020 19:53:46

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:10', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2801682e-1e35-4124-9855-9486ff157565' User entered 'None (1)'	System	24 Sep 2020 23:27:33
	System	24 Sep 2020 23:27:33

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:11:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:20', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2801682e-1e35-4124-9855-9486ff157565' User entered 'No (N)'	System	24 Sep 2020 23:27:33
	System	24 Sep 2020 23:27:33

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:23', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2801682e-1e35-4124-9855-9486ff157565' User entered 'No (N)'	System	24 Sep 2020 23:27:33
	System	24 Sep 2020 23:27:33

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:27', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2801682e-1e35-4124-9855-9486ff157565' User entered 'None (1)'	System	24 Sep 2020 23:27:33
	System	24 Sep 2020 23:27:33

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:29', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2801682e-1e35-4124-9855-9486ff157565' User entered '24 Sep 2020 19:27'	System	24 Sep 2020 23:27:33
	System	24 Sep 2020 23:27:33



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 5'	System	21 Sep 2020 19:53:46

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:26:59', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9f35059e-d793-4142-80a9-14dc0dc73d2b' User entered 'None (1)'	System	26 Sep 2020 00:27:20
	System	26 Sep 2020 00:27:20

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:03', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9f35059e-d793-4142-80a9-14dc0dc73d2b' User entered 'No (N)'	System	26 Sep 2020 00:27:20
	System	26 Sep 2020 00:27:20

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:09', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9f35059e-d793-4142-80a9-14dc0dc73d2b' User entered 'No (N)'	System	26 Sep 2020 00:27:20
	System	26 Sep 2020 00:27:20

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:12', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9f35059e-d793-4142-80a9-14dc0dc73d2b' User entered 'None (1)'	System	26 Sep 2020 00:27:20
	System	26 Sep 2020 00:27:20

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:16', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9f35059e-d793-4142-80a9-14dc0dc73d2b' User entered '25 Sep 2020 20:27'	System	26 Sep 2020 00:27:20
	System	26 Sep 2020 00:27:20



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 6'	System	21 Sep 2020 19:53:46

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:10', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f5b3317f-b5bd-43ef-b163-537cb66e0e67'	System	27 Sep 2020 00:43:26
User entered 'None (1)'	System	27 Sep 2020 00:43:26

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f5b3317f-b5bd-43ef-b163-537cb66e0e67' User entered 'No (N)'	System	27 Sep 2020 00:43:26
	System	27 Sep 2020 00:43:26

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:16', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f5b3317f-b5bd-43ef-b163-537cb66e0e67' User entered 'No (N)'	System	27 Sep 2020 00:43:26
	System	27 Sep 2020 00:43:26

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:19', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f5b3317f-b5bd-43ef-b163-537cb66e0e67' User entered 'None (1)'	System	27 Sep 2020 00:43:26
	System	27 Sep 2020 00:43:26

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:24', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f5b3317f-b5bd-43ef-b163-537cb66e0e67' User entered '26 Sep 2020 20:43'	System	27 Sep 2020 00:43:26
	System	27 Sep 2020 00:43:26



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 7'	System	21 Sep 2020 19:53:46

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:30:45', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '820609d5-a9f1-4973-9e50-e2349e2b21de' User entered 'None (1)'	System	27 Sep 2020 18:31:06
	System	27 Sep 2020 18:31:06

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:11:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:30:48', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '820609d5-a9f1-4973-9e50-e2349e2b21de' User entered 'No (N)'	System	27 Sep 2020 18:31:06
	System	27 Sep 2020 18:31:06

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:30:53', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '820609d5-a9f1-4973-9e50-e2349e2b21de' User entered 'No (N)'	System	27 Sep 2020 18:31:06
	System	27 Sep 2020 18:31:06

US3602074

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:01', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '820609d5-a9f1-4973-9e50-e2349e2b21de' User entered 'None (1)'	System	27 Sep 2020 18:31:06
	System	27 Sep 2020 18:31:06

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:04', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '820609d5-a9f1-4973-9e50-e2349e2b21de' User entered '27 Sep 2020 14:31'	System	27 Sep 2020 18:31:06
	System	27 Sep 2020 18:31:06



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:29:19', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '12617629-8e51-4189-be8c-13943413aa07' User entered 'None (0)'	System	21 Sep 2020 20:29:59
	System	21 Sep 2020 20:29:59

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:29:25', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '12617629-8e51-4189-be8c-13943413aa07' User entered 'None (0)'	System	21 Sep 2020 20:29:59
	System	21 Sep 2020 20:29:59

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:29:32', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '12617629-8e51-4189-be8c-13943413aa07' User entered 'None (0)'	System	21 Sep 2020 20:29:59
	System	21 Sep 2020 20:29:59

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:29:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '12617629-8e51-4189-be8c-13943413aa07' User entered 'None (0)'	System	21 Sep 2020 20:29:59
	System	21 Sep 2020 20:29:59

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:29:40', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '12617629-8e51-4189-be8c-13943413aa07' User entered 'None (0)'	System	21 Sep 2020 20:29:59
	System	21 Sep 2020 20:29:59



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:29:42', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '12617629-8e51-4189-be8c-13943413aa07' User entered 'None (0)'	System	21 Sep 2020 20:29:59
	System	21 Sep 2020 20:29:59

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:29:52', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '12617629-8e51-4189-be8c-13943413aa07'	System	21 Sep 2020 20:29:59
User entered 'No (N)'	System	21 Sep 2020 20:29:59

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T16:29:55', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '12617629-8e51-4189-be8c-13943413aa07'	System	21 Sep 2020 20:29:59
User entered '21 Sep 2020 16:29'	System	21 Sep 2020 20:29:59

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Sep 2020 16:10'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Sep 2020 18:40'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:32:48', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ea49ae08-3a1e-450f-b9aa-4dd35c68a9a1' User entered 'None (0)'	System	22 Sep 2020 00:33:23
	System	22 Sep 2020 00:33:23

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:32:52', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ea49ae08-3a1e-450f-b9aa-4dd35c68a9a1' User entered 'None (0)'	System	22 Sep 2020 00:33:23
	System	22 Sep 2020 00:33:23



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:32:56', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ea49ae08-3a1e-450f-b9aa-4dd35c68a9a1' User entered 'None (0)'	System	22 Sep 2020 00:33:23
	System	22 Sep 2020 00:33:23

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:33:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ea49ae08-3a1e-450f-b9aa-4dd35c68a9a1' User entered 'None (0)'	System	22 Sep 2020 00:33:23
	System	22 Sep 2020 00:33:23

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:33:05', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ea49ae08-3a1e-450f-b9aa-4dd35c68a9a1' User entered 'None (0)'	System	22 Sep 2020 00:33:23
	System	22 Sep 2020 00:33:23

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:33:08', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ea49ae08-3a1e-450f-b9aa-4dd35c68a9a1' User entered 'None (0)'	System	22 Sep 2020 00:33:23
	System	22 Sep 2020 00:33:23

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:33:16', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ea49ae08-3a1e-450f-b9aa-4dd35c68a9a1' User entered 'No (N)'	System	22 Sep 2020 00:33:23
	System	22 Sep 2020 00:33:23

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-21T20:33:20', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ea49ae08-3a1e-450f-b9aa-4dd35c68a9a1' User entered '21 Sep 2020 20:33'	System	22 Sep 2020 00:33:23
	System	22 Sep 2020 00:33:23

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Sep 2020 19:35'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 19:53:46



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 2'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:51', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b63c540e-8035-4abf-936b-9dad240d4d4d' User entered 'None (0)'	System	23 Sep 2020 01:25:30
	System	23 Sep 2020 01:25:30

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:54', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b63c540e-8035-4abf-936b-9dad240d4d4d' User entered 'None (0)'	System	23 Sep 2020 01:25:30
	System	23 Sep 2020 01:25:30

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:24:59', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b63c540e-8035-4abf-936b-9dad240d4d4d' User entered 'None (0)'	System	23 Sep 2020 01:25:30
	System	23 Sep 2020 01:25:30

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:25:03', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b63c540e-8035-4abf-936b-9dad240d4d4d' User entered 'None (0)'	System	23 Sep 2020 01:25:30
	System	23 Sep 2020 01:25:30

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:25:06', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b63c540e-8035-4abf-936b-9dad240d4d4d' User entered 'None (0)'	System	23 Sep 2020 01:25:30
	System	23 Sep 2020 01:25:30

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:25:08', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b63c540e-8035-4abf-936b-9dad240d4d4d' User entered 'None (0)'	System	23 Sep 2020 01:25:30
	System	23 Sep 2020 01:25:30

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:25:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b63c540e-8035-4abf-936b-9dad240d4d4d' User entered 'No (N)'	System	23 Sep 2020 01:25:30
	System	23 Sep 2020 01:25:30



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-22T21:25:27', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b63c540e-8035-4abf-936b-9dad240d4d4d' User entered '22 Sep 2020 21:25'	System	23 Sep 2020 01:25:30
	System	23 Sep 2020 01:25:30

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 3'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:53', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55dc7dda-5c36-446c-b8ae-e6f3cf49ee13' User entered 'None (0)'	System	24 Sep 2020 01:11:19
	System	24 Sep 2020 01:11:19

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:56', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55dc7dda-5c36-446c-b8ae-e6f3cf49ee13' User entered 'None (0)'	System	24 Sep 2020 01:11:19
	System	24 Sep 2020 01:11:19

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:10:59', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55dc7dda-5c36-446c-b8ae-e6f3cf49ee13' User entered 'None (0)'	System	24 Sep 2020 01:11:19
	System	24 Sep 2020 01:11:19

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:11:02', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55dc7dda-5c36-446c-b8ae-e6f3cf49ee13' User entered 'None (0)'	System	24 Sep 2020 01:11:19
	System	24 Sep 2020 01:11:19



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:11:04', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55dc7dda-5c36-446c-b8ae-e6f3cf49ee13' User entered 'None (0)'	System	24 Sep 2020 01:11:19
	System	24 Sep 2020 01:11:19

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:11:07', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55dc7dda-5c36-446c-b8ae-e6f3cf49ee13' User entered 'None (0)'	System	24 Sep 2020 01:11:19
	System	24 Sep 2020 01:11:19

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:11:11', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55dc7dda-5c36-446c-b8ae-e6f3cf49ee13' User entered 'No (N)'	System	24 Sep 2020 01:11:19
	System	24 Sep 2020 01:11:19

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-23T21:11:15', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55dc7dda-5c36-446c-b8ae-e6f3cf49ee13' User entered '23 Sep 2020 21:11'	System	24 Sep 2020 01:11:19
	System	24 Sep 2020 01:11:19

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 4'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:43', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ddb10920-bb59-4dbc-ba19-d38426dd6a21' User entered 'None (0)'	System	24 Sep 2020 23:28:11
	System	24 Sep 2020 23:28:11



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:47', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ddb10920-bb59-4dbc-ba19-d38426dd6a21' User entered 'None (0)'	System	24 Sep 2020 23:28:11
	System	24 Sep 2020 23:28:11

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:51', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ddb10920-bb59-4dbc-ba19-d38426dd6a21' User entered 'None (0)'	System	24 Sep 2020 23:28:11
	System	24 Sep 2020 23:28:11

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:11:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:54', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ddb10920-bb59-4dbc-ba19-d38426dd6a21' User entered 'None (0)'	System	24 Sep 2020 23:28:11
	System	24 Sep 2020 23:28:11

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:27:57', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ddb10920-bb59-4dbc-ba19-d38426dd6a21' User entered 'None (0)'	System	24 Sep 2020 23:28:11
	System	24 Sep 2020 23:28:11

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:28:01', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ddb10920-bb59-4dbc-ba19-d38426dd6a21' User entered 'None (0)'	System	24 Sep 2020 23:28:11
	System	24 Sep 2020 23:28:11

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:28:05', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ddb10920-bb59-4dbc-ba19-d38426dd6a21'	System	24 Sep 2020 23:28:11
User entered 'No (N)'	System	24 Sep 2020 23:28:11

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-24T19:28:09', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ddb10920-bb59-4dbc-ba19-d38426dd6a21' User entered '24 Sep 2020 19:28'	System	24 Sep 2020 23:28:11
	System	24 Sep 2020 23:28:11

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 19:53:46



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 5'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:22', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9e86d276-7b85-40cb-8436-222d9aafb996' User entered 'None (0)'	System	26 Sep 2020 00:27:43
	System	26 Sep 2020 00:27:43

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:24', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9e86d276-7b85-40cb-8436-222d9aafb996' User entered 'None (0)'	System	26 Sep 2020 00:27:43
	System	26 Sep 2020 00:27:43

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:27', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9e86d276-7b85-40cb-8436-222d9aafb996' User entered 'None (0)'	System	26 Sep 2020 00:27:43
	System	26 Sep 2020 00:27:43

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:29', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9e86d276-7b85-40cb-8436-222d9aafb996' User entered 'None (0)'	System	26 Sep 2020 00:27:43
	System	26 Sep 2020 00:27:43

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:31', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9e86d276-7b85-40cb-8436-222d9aafb996' User entered 'None (0)'	System	26 Sep 2020 00:27:43
	System	26 Sep 2020 00:27:43

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:34', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9e86d276-7b85-40cb-8436-222d9aafb996' User entered 'None (0)'	System	26 Sep 2020 00:27:43
	System	26 Sep 2020 00:27:43



US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9e86d276-7b85-40cb-8436-222d9aafb996'	System	26 Sep 2020 00:27:43
User entered 'No (N)'	System	26 Sep 2020 00:27:43

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-25T20:27:41', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9e86d276-7b85-40cb-8436-222d9aafb996'	System	26 Sep 2020 00:27:43
User entered '25 Sep 2020 20:27'	System	26 Sep 2020 00:27:43

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 6'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:28', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '593d6a01-6b79-4283-b8b3-99cd7b363d57' User entered 'None (0)'	System	27 Sep 2020 00:43:51
	System	27 Sep 2020 00:43:51

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:30', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '593d6a01-6b79-4283-b8b3-99cd7b363d57' User entered 'None (0)'	System	27 Sep 2020 00:43:51
	System	27 Sep 2020 00:43:51

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:33', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '593d6a01-6b79-4283-b8b3-99cd7b363d57' User entered 'None (0)'	System	27 Sep 2020 00:43:51
	System	27 Sep 2020 00:43:51



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:36', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '593d6a01-6b79-4283-b8b3-99cd7b363d57' User entered 'None (0)'	System	27 Sep 2020 00:43:51
	System	27 Sep 2020 00:43:51

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:39', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '593d6a01-6b79-4283-b8b3-99cd7b363d57' User entered 'None (0)'	System	27 Sep 2020 00:43:51
	System	27 Sep 2020 00:43:51

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:41', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '593d6a01-6b79-4283-b8b3-99cd7b363d57' User entered 'None (0)'	System	27 Sep 2020 00:43:51
	System	27 Sep 2020 00:43:51

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:45', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '593d6a01-6b79-4283-b8b3-99cd7b363d57'	System	27 Sep 2020 00:43:51
User entered 'No (N)'	System	27 Sep 2020 00:43:51

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-26T20:43:49', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '593d6a01-6b79-4283-b8b3-99cd7b363d57'	System	27 Sep 2020 00:43:51
User entered '26 Sep 2020 20:43'	System	27 Sep 2020 00:43:51

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	21 Sep 2020 19:53:46
User entered 'Day 7'	System	21 Sep 2020 19:53:46



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:09', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d7707fe-1849-42ec-8783-3da6e3dc52d3' User entered 'None (0)'	System	27 Sep 2020 18:31:33
	System	27 Sep 2020 18:31:33

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:12', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d7707fe-1849-42ec-8783-3da6e3dc52d3' User entered 'None (0)'	System	27 Sep 2020 18:31:33
	System	27 Sep 2020 18:31:33

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:15', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d7707fe-1849-42ec-8783-3da6e3dc52d3' User entered 'None (0)'	System	27 Sep 2020 18:31:33
	System	27 Sep 2020 18:31:33

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:18', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d7707fe-1849-42ec-8783-3da6e3dc52d3' User entered 'None (0)'	System	27 Sep 2020 18:31:33
	System	27 Sep 2020 18:31:33

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:20', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d7707fe-1849-42ec-8783-3da6e3dc52d3' User entered 'None (0)'	System	27 Sep 2020 18:31:33
	System	27 Sep 2020 18:31:33

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:22', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d7707fe-1849-42ec-8783-3da6e3dc52d3' User entered 'None (0)'	System	27 Sep 2020 18:31:33
	System	27 Sep 2020 18:31:33

US3602074

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:25', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d7707fe-1849-42ec-8783-3da6e3dc52d3' User entered 'No (N)'	System	27 Sep 2020 18:31:33
	System	27 Sep 2020 18:31:33

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-09-27T14:31:29', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d7707fe-1849-42ec-8783-3da6e3dc52d3' User entered '27 Sep 2020 14:31'	System	27 Sep 2020 18:31:33
	System	27 Sep 2020 18:31:33



**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 19:53:46

**US3602074**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:10:19

**US3602074**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:10:19

**US3602074**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:10:19

**US3602074**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:10:19

**US3602074**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:10:24

**US3602074**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	30 Sep 2020 16:10:24



**US3602074**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:54:42

**US3602074**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:54:42

**US3602074**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:54:42

**US3602074**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:54:42

**US3602074**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:56:32

**US3602074**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	19 Oct 2020 19:56:32

**US3602074**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:55:27

**US3602074**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:55:27



**US3602074**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:55:27

**US3602074**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:55:27

**US3602074**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:56:40

**US3602074**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	19 Oct 2020 19:56:40

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:56:51

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:56:51

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:56:51

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'VISIT2'	System	19 Oct 2020 19:56:51



**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '13:37'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '19 Oct 2020 13:37'	System	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42



**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '90'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'bpm'	System	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '18'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'breaths/min'	System	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '124'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '84'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:05:42

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	19 Oct 2020 20:05:42



**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '15:47'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '19 Oct 2020 15:47'	System	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47



**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '72'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'bpm'	System	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'breaths/min'	System	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '116'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '76'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:38:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	17 Nov 2020 17:38:47



**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:06:04

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:06:04

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:59:07

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:59:07

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:59:07

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'MRNA-1273 OR PLACEBO'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:59:07

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '15:17'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:59:07



**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '19 Oct 2020 15:17'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:59:07

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'ONCE'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'INTRAMUSCULAR'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:06:15

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:06:15

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '13:37'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:06:15

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '19 Oct 2020 13:37'	System	19 Oct 2020 20:06:15



**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:11:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:07:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Oct 2020 20:07:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:07:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '13:37'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:07:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '19 Oct 2020 13:37'	System	19 Oct 2020 20:07:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Oct 2020 20:07:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:07:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:07:47



**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered empty.	System	19 Oct 2020 20:07:47

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:07:53

**US3602074**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	19 Oct 2020 20:07:53

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T15:59:26', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a0fa4280-bc7d-4ad3-8bdd-9f5dc09a7bdf' User entered 'Yes (Y)'	System	19 Oct 2020 19:59:47
	System	19 Oct 2020 19:59:47

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T15:59:31', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a0fa4280-bc7d-4ad3-8bdd-9f5dc09a7bdf' User entered '97.1'	System	19 Oct 2020 19:59:47
	System	19 Oct 2020 19:59:47

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T15:59:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a0fa4280-bc7d-4ad3-8bdd-9f5dc09a7bdf'	System	19 Oct 2020 19:59:47
User entered 'No (N)'	System	19 Oct 2020 19:59:47

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T15:59:41', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a0fa4280-bc7d-4ad3-8bdd-9f5dc09a7bdf' User entered '19 Oct 2020 15:59'	System	19 Oct 2020 19:59:47
	System	19 Oct 2020 19:59:47



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '19 Oct 2020 15:37'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '19 Oct 2020 18:07'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:01', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55479baf-bfe2-48b5-a6e6-499f1056a776'	System	20 Oct 2020 00:15:19
User entered 'Yes (Y)'	System	20 Oct 2020 00:15:19

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:06', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55479baf-bfe2-48b5-a6e6-499f1056a776' User entered '98.6'	System	20 Oct 2020 00:15:19
	System	20 Oct 2020 00:15:19

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:09', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55479baf-bfe2-48b5-a6e6-499f1056a776'	System	20 Oct 2020 00:15:19
User entered 'No (N)'	System	20 Oct 2020 00:15:19

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:14', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '55479baf-bfe2-48b5-a6e6-499f1056a776' User entered '19 Oct 2020 20:15'	System	20 Oct 2020 00:15:19
	System	20 Oct 2020 00:15:19

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '19 Oct 2020 19:02'	System	19 Oct 2020 19:59:07



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 2'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:54:12', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '960ca7fa-c8ca-4bc0-a7ee-79cb95f46323' User entered 'Yes (Y)'	System	21 Oct 2020 00:54:27
	System	21 Oct 2020 00:54:27

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:54:17', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '960ca7fa-c8ca-4bc0-a7ee-79cb95f46323' User entered '98.1'	System	21 Oct 2020 00:54:27
	System	21 Oct 2020 00:54:27

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:54:21', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '960ca7fa-c8ca-4bc0-a7ee-79cb95f46323'	System	21 Oct 2020 00:54:27
User entered 'No (N)'	System	21 Oct 2020 00:54:27

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:54:25', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '960ca7fa-c8ca-4bc0-a7ee-79cb95f46323' User entered '20 Oct 2020 20:54'	System	21 Oct 2020 00:54:27
	System	21 Oct 2020 00:54:27

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 19:59:07



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 3'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:56:02', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f6494cd5-19c2-474d-8ffe-332ef61b1efb' User entered 'Yes (Y)'	System	22 Oct 2020 00:56:14
	System	22 Oct 2020 00:56:14

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:56:06', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f6494cd5-19c2-474d-8ffe-332ef61b1efb' User entered '97.8'	System	22 Oct 2020 00:56:14
	System	22 Oct 2020 00:56:14

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:56:10', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f6494cd5-19c2-474d-8ffe-332ef61b1efb'	System	22 Oct 2020 00:56:14
User entered 'No (N)'	System	22 Oct 2020 00:56:14

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:56:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f6494cd5-19c2-474d-8ffe-332ef61b1efb'	System	22 Oct 2020 00:56:14
User entered '21 Oct 2020 20:56'	System	22 Oct 2020 00:56:14

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 4'	System	19 Oct 2020 19:59:07



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:12:57', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '74fef9db-e65e-481c-86a1-22a8ea83916c' User entered 'Yes (Y)'	System	23 Oct 2020 01:13:44
	System	23 Oct 2020 01:13:44

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:13:24', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '74fef9db-e65e-481c-86a1-22a8ea83916c' User entered '97.8'	System	23 Oct 2020 01:13:44
	System	23 Oct 2020 01:13:44

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:13:34', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '74fef9db-e65e-481c-86a1-22a8ea83916c' User entered 'No (N)'	System	23 Oct 2020 01:13:44
	System	23 Oct 2020 01:13:44

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:13:39', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '74fef9db-e65e-481c-86a1-22a8ea83916c' User entered '22 Oct 2020 21:13'	System	23 Oct 2020 01:13:44
	System	23 Oct 2020 01:13:44

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 5'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:04', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '083c652b-fb14-4e47-a701-e03f476c10e1' User entered 'Yes (Y)'	System	23 Oct 2020 20:57:20
	System	23 Oct 2020 20:57:20



US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:12', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '083c652b-fb14-4e47-a701-e03f476c10e1' User entered '98.1'	System	23 Oct 2020 20:57:20
	System	23 Oct 2020 20:57:20

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:15', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '083c652b-fb14-4e47-a701-e03f476c10e1' User entered 'No (N)'	System	23 Oct 2020 20:57:20
	System	23 Oct 2020 20:57:20

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:18', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '083c652b-fb14-4e47-a701-e03f476c10e1' User entered '23 Oct 2020 16:57'	System	23 Oct 2020 20:57:20
	System	23 Oct 2020 20:57:20

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 6'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:30:42', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '24123478-4a7a-45f6-8fa2-4aa441e135d0' User entered 'Yes (Y)'	System	25 Oct 2020 01:30:59
	System	25 Oct 2020 01:30:59

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:30:46', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '24123478-4a7a-45f6-8fa2-4aa441e135d0' User entered '98.1'	System	25 Oct 2020 01:30:59
	System	25 Oct 2020 01:30:59



US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:30:49', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '24123478-4a7a-45f6-8fa2-4aa441e135d0' User entered 'No (N)'	System	25 Oct 2020 01:30:59
	System	25 Oct 2020 01:30:59

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:30:54', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '24123478-4a7a-45f6-8fa2-4aa441e135d0' User entered '24 Oct 2020 21:30'	System	25 Oct 2020 01:30:59
	System	25 Oct 2020 01:30:59

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 7'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:21:52', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d6b4322-5921-498e-b2b5-1311dad68851' User entered 'Yes (Y)'	System	26 Oct 2020 02:22:46
	System	26 Oct 2020 02:22:46

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:11:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:22:36', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d6b4322-5921-498e-b2b5-1311dad68851' User entered '97.9'	System	26 Oct 2020 02:22:46
	System	26 Oct 2020 02:22:46

US3602074

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:22:39', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d6b4322-5921-498e-b2b5-1311dad68851'	System	26 Oct 2020 02:22:46
User entered 'No (N)'	System	26 Oct 2020 02:22:46



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:22:42', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8d6b4322-5921-498e-b2b5-1311dad68851' User entered '25 Oct 2020 22:22'	System	26 Oct 2020 02:22:46
	System	26 Oct 2020 02:22:46

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 19:59:07

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:14', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0688c71-6090-4ced-9dd6-52e63321e2e7' User entered 'None (1)'	System	19 Oct 2020 20:00:38
	System	19 Oct 2020 20:00:38

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:18', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0688c71-6090-4ced-9dd6-52e63321e2e7'	System	19 Oct 2020 20:00:38
User entered 'No (N)'	System	19 Oct 2020 20:00:38

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:23', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0688c71-6090-4ced-9dd6-52e63321e2e7' User entered 'No (N)'	System	19 Oct 2020 20:00:38
	System	19 Oct 2020 20:00:38

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:28', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0688c71-6090-4ced-9dd6-52e63321e2e7' User entered 'None (1)'	System	19 Oct 2020 20:00:38
	System	19 Oct 2020 20:00:38



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:32', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0688c71-6090-4ced-9dd6-52e63321e2e7' User entered '19 Oct 2020 16:00'	System	19 Oct 2020 20:00:38
	System	19 Oct 2020 20:00:38

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '19 Oct 2020 15:37'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '19 Oct 2020 18:07'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 19:59:07

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:34', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2f021918-1923-4bd1-86ae-423412e6ae46' User entered 'None (1)'	System	20 Oct 2020 00:15:53
	System	20 Oct 2020 00:15:53

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:38', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2f021918-1923-4bd1-86ae-423412e6ae46' User entered 'No (N)'	System	20 Oct 2020 00:15:53
	System	20 Oct 2020 00:15:53

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:41', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2f021918-1923-4bd1-86ae-423412e6ae46' User entered 'No (N)'	System	20 Oct 2020 00:15:53
	System	20 Oct 2020 00:15:53

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:47', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2f021918-1923-4bd1-86ae-423412e6ae46' User entered 'None (1)'	System	20 Oct 2020 00:15:53
	System	20 Oct 2020 00:15:53



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:51', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2f021918-1923-4bd1-86ae-423412e6ae46' User entered '19 Oct 2020 20:15'	System	20 Oct 2020 00:15:53
	System	20 Oct 2020 00:15:53

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '19 Oct 2020 19:02'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 2'	System	19 Oct 2020 19:59:07

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:54:36', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0057191-1c92-4b1c-8a7d-1ce6854d3871' User entered 'None (1)'	System	21 Oct 2020 00:54:58
	System	21 Oct 2020 00:54:58

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:54:39', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0057191-1c92-4b1c-8a7d-1ce6854d3871' User entered 'No (N)'	System	21 Oct 2020 00:54:58
	System	21 Oct 2020 00:54:58

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:54:43', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0057191-1c92-4b1c-8a7d-1ce6854d3871' User entered 'No (N)'	System	21 Oct 2020 00:54:58
	System	21 Oct 2020 00:54:58

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:54:53', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0057191-1c92-4b1c-8a7d-1ce6854d3871' User entered 'None (1)'	System	21 Oct 2020 00:54:58
	System	21 Oct 2020 00:54:58



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:54:56', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f0057191-1c92-4b1c-8a7d-1ce6854d3871' User entered '20 Oct 2020 20:54'	System	21 Oct 2020 00:54:58
	System	21 Oct 2020 00:54:58

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 3'	System	19 Oct 2020 19:59:07

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:56:30', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '79228f37-d00d-4ff3-9cb4-510804fa32d4'	System	22 Oct 2020 00:57:03
User entered 'None (1)'	System	22 Oct 2020 00:57:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:56:42', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '79228f37-d00d-4ff3-9cb4-510804fa32d4' User entered 'No (N)'	System	22 Oct 2020 00:57:03
	System	22 Oct 2020 00:57:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:56:45', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '79228f37-d00d-4ff3-9cb4-510804fa32d4'	System	22 Oct 2020 00:57:03
User entered 'No (N)'	System	22 Oct 2020 00:57:03

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:56:55', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '79228f37-d00d-4ff3-9cb4-510804fa32d4'	System	22 Oct 2020 00:57:03
User entered 'None (1)'	System	22 Oct 2020 00:57:03



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:56:59', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '79228f37-d00d-4ff3-9cb4-510804fa32d4' User entered '21 Oct 2020 20:56'	System	22 Oct 2020 00:57:03
	System	22 Oct 2020 00:57:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 4'	System	19 Oct 2020 19:59:07

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:13:44', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a6092f7b-0c6f-42f8-b7c2-3b31402cfadf' User entered 'None (1)'	System	23 Oct 2020 01:14:10
	System	23 Oct 2020 01:14:10

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:13:49', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a6092f7b-0c6f-42f8-b7c2-3b31402cfadf' User entered 'No (N)'	System	23 Oct 2020 01:14:10
	System	23 Oct 2020 01:14:10

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:13:58', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a6092f7b-0c6f-42f8-b7c2-3b31402cfadf' User entered 'No (N)'	System	23 Oct 2020 01:14:10
	System	23 Oct 2020 01:14:10

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:03', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a6092f7b-0c6f-42f8-b7c2-3b31402cfadf' User entered 'None (1)'	System	23 Oct 2020 01:14:10
	System	23 Oct 2020 01:14:10



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:06', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a6092f7b-0c6f-42f8-b7c2-3b31402cfadf' User entered '22 Oct 2020 21:14'	System	23 Oct 2020 01:14:10
	System	23 Oct 2020 01:14:10

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 5'	System	19 Oct 2020 19:59:07

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:28', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '0442b7c6-3829-40d0-8ef8-3b52db4edc37'	System	23 Oct 2020 20:57:54
User entered 'None (1)'	System	23 Oct 2020 20:57:54

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:35', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '0442b7c6-3829-40d0-8ef8-3b52db4edc37' User entered 'No (N)'	System	23 Oct 2020 20:57:54
	System	23 Oct 2020 20:57:54

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:43', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '0442b7c6-3829-40d0-8ef8-3b52db4edc37' User entered 'No (N)'	System	23 Oct 2020 20:57:54
	System	23 Oct 2020 20:57:54

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:48', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '0442b7c6-3829-40d0-8ef8-3b52db4edc37'	System	23 Oct 2020 20:57:54
User entered 'None (1)'	System	23 Oct 2020 20:57:54



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:52', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '0442b7c6-3829-40d0-8ef8-3b52db4edc37' User entered '23 Oct 2020 16:57'	System	23 Oct 2020 20:57:54
	System	23 Oct 2020 20:57:54

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 6'	System	19 Oct 2020 19:59:07

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:30:59', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '012bc255-86d8-44ab-8cc1-40d77b5e3be6' User entered 'None (1)'	System	25 Oct 2020 01:31:16
	System	25 Oct 2020 01:31:16

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:03', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '012bc255-86d8-44ab-8cc1-40d77b5e3be6' User entered 'No (N)'	System	25 Oct 2020 01:31:16
	System	25 Oct 2020 01:31:16

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:08', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '012bc255-86d8-44ab-8cc1-40d77b5e3be6' User entered 'No (N)'	System	25 Oct 2020 01:31:16
	System	25 Oct 2020 01:31:16

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:12', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '012bc255-86d8-44ab-8cc1-40d77b5e3be6' User entered 'None (1)'	System	25 Oct 2020 01:31:16
	System	25 Oct 2020 01:31:16



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:15', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '012bc255-86d8-44ab-8cc1-40d77b5e3be6' User entered '24 Oct 2020 21:31'	System	25 Oct 2020 01:31:16
	System	25 Oct 2020 01:31:16

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 7'	System	19 Oct 2020 19:59:07

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:22:47', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '87dac5b3-21a9-4283-b4d1-4f2d976b087d' User entered 'None (1)'	System	26 Oct 2020 02:23:03
	System	26 Oct 2020 02:23:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:22:51', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '87dac5b3-21a9-4283-b4d1-4f2d976b087d' User entered 'No (N)'	System	26 Oct 2020 02:23:03
	System	26 Oct 2020 02:23:03

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:22:54', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '87dac5b3-21a9-4283-b4d1-4f2d976b087d' User entered 'No (N)'	System	26 Oct 2020 02:23:03
	System	26 Oct 2020 02:23:03

US3602074

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:22:58', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '87dac5b3-21a9-4283-b4d1-4f2d976b087d' User entered 'None (1)'	System	26 Oct 2020 02:23:03
	System	26 Oct 2020 02:23:03



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:23:01', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '87dac5b3-21a9-4283-b4d1-4f2d976b087d' User entered '25 Oct 2020 22:23'	System	26 Oct 2020 02:23:03
	System	26 Oct 2020 02:23:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:39', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cc767ecf-d415-4f20-85ef-1fe4a7acdbf1' User entered 'None (0)'	System	19 Oct 2020 20:01:08
	System	19 Oct 2020 20:01:08

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:42', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cc767ecf-d415-4f20-85ef-1fe4a7acdbf1' User entered 'None (0)'	System	19 Oct 2020 20:01:08
	System	19 Oct 2020 20:01:08

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:45', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cc767ecf-d415-4f20-85ef-1fe4a7acdbf1' User entered 'None (0)'	System	19 Oct 2020 20:01:08
	System	19 Oct 2020 20:01:08

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:48', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cc767ecf-d415-4f20-85ef-1fe4a7acdbf1' User entered 'None (0)'	System	19 Oct 2020 20:01:08
	System	19 Oct 2020 20:01:08



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:50', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cc767ecf-d415-4f20-85ef-1fe4a7acdbf1' User entered 'None (0)'	System	19 Oct 2020 20:01:08
	System	19 Oct 2020 20:01:08

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:53', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cc767ecf-d415-4f20-85ef-1fe4a7acdbf1' User entered 'None (0)'	System	19 Oct 2020 20:01:08
	System	19 Oct 2020 20:01:08

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:00:57', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cc767ecf-d415-4f20-85ef-1fe4a7acdbf1'	System	19 Oct 2020 20:01:08
User entered 'No (N)'	System	19 Oct 2020 20:01:08

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T16:01:01', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cc767ecf-d415-4f20-85ef-1fe4a7acdbf1'	System	19 Oct 2020 20:01:08
User entered '19 Oct 2020 16:01'	System	19 Oct 2020 20:01:08

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '19 Oct 2020 15:37'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '19 Oct 2020 18:07'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:15:56', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e2032cd0-f4d2-4e82-b234-e0d2b59b993e' User entered 'None (0)'	System	20 Oct 2020 00:17:03
	System	20 Oct 2020 00:17:03



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:16:17', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e2032cd0-f4d2-4e82-b234-e0d2b59b993e'	System	20 Oct 2020 00:17:03
User entered 'No interference with activity (1)'	System	20 Oct 2020 00:17:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:16:21', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e2032cd0-f4d2-4e82-b234-e0d2b59b993e' User entered 'None (0)'	System	20 Oct 2020 00:17:03
	System	20 Oct 2020 00:17:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:16:27', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e2032cd0-f4d2-4e82-b234-e0d2b59b993e' User entered 'None (0)'	System	20 Oct 2020 00:17:03
	System	20 Oct 2020 00:17:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:16:31', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e2032cd0-f4d2-4e82-b234-e0d2b59b993e' User entered 'None (0)'	System	20 Oct 2020 00:17:03
	System	20 Oct 2020 00:17:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:16:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e2032cd0-f4d2-4e82-b234-e0d2b59b993e' User entered 'None (0)'	System	20 Oct 2020 00:17:03
	System	20 Oct 2020 00:17:03

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:16:42', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e2032cd0-f4d2-4e82-b234-e0d2b59b993e' User entered 'No (N)'	System	20 Oct 2020 00:17:03
	System	20 Oct 2020 00:17:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-19T20:16:48', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e2032cd0-f4d2-4e82-b234-e0d2b59b993e' User entered '19 Oct 2020 20:16'	System	20 Oct 2020 00:17:03
	System	20 Oct 2020 00:17:03

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '19 Oct 2020 19:02'	System	19 Oct 2020 19:59:07



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 2'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:55:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9d4920e1-b829-48b5-9a59-98822536b458' User entered 'None (0)'	System	21 Oct 2020 00:55:24
	System	21 Oct 2020 00:55:24

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:55:04', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9d4920e1-b829-48b5-9a59-98822536b458'	System	21 Oct 2020 00:55:24
User entered 'No interference with activity (1)'	System	21 Oct 2020 00:55:24

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:55:07', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9d4920e1-b829-48b5-9a59-98822536b458' User entered 'None (0)'	System	21 Oct 2020 00:55:24
	System	21 Oct 2020 00:55:24

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:11:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:55:10', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9d4920e1-b829-48b5-9a59-98822536b458' User entered 'None (0)'	System	21 Oct 2020 00:55:24
	System	21 Oct 2020 00:55:24

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:55:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9d4920e1-b829-48b5-9a59-98822536b458' User entered 'None (0)'	System	21 Oct 2020 00:55:24
	System	21 Oct 2020 00:55:24

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:55:15', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9d4920e1-b829-48b5-9a59-98822536b458' User entered 'None (0)'	System	21 Oct 2020 00:55:24
	System	21 Oct 2020 00:55:24



US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:55:18', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9d4920e1-b829-48b5-9a59-98822536b458' User entered 'No (N)'	System	21 Oct 2020 00:55:24
	System	21 Oct 2020 00:55:24

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-20T20:55:21', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9d4920e1-b829-48b5-9a59-98822536b458' User entered '20 Oct 2020 20:55'	System	21 Oct 2020 00:55:24
	System	21 Oct 2020 00:55:24

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 3'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:57:03', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8f57f8f4-0f8c-47df-895b-d91f19db7b98' User entered 'None (0)'	System	22 Oct 2020 00:57:26
	System	22 Oct 2020 00:57:26

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:57:05', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8f57f8f4-0f8c-47df-895b-d91f19db7b98'	System	22 Oct 2020 00:57:26
User entered 'None (0)'	System	22 Oct 2020 00:57:26

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:57:08', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8f57f8f4-0f8c-47df-895b-d91f19db7b98'	System	22 Oct 2020 00:57:26
User entered 'None (0)'	System	22 Oct 2020 00:57:26



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:57:10', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8f57f8f4-0f8c-47df-895b-d91f19db7b98' User entered 'None (0)'	System	22 Oct 2020 00:57:26
	System	22 Oct 2020 00:57:26

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:57:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8f57f8f4-0f8c-47df-895b-d91f19db7b98'	System	22 Oct 2020 00:57:26
User entered 'None (0)'	System	22 Oct 2020 00:57:26

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:57:17', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8f57f8f4-0f8c-47df-895b-d91f19db7b98'	System	22 Oct 2020 00:57:26
User entered 'None (0)'	System	22 Oct 2020 00:57:26

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:57:20', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8f57f8f4-0f8c-47df-895b-d91f19db7b98'	System	22 Oct 2020 00:57:26
User entered 'No (N)'	System	22 Oct 2020 00:57:26

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-21T20:57:24', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8f57f8f4-0f8c-47df-895b-d91f19db7b98'	System	22 Oct 2020 00:57:26
User entered '21 Oct 2020 20:57'	System	22 Oct 2020 00:57:26

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 4'	System	19 Oct 2020 19:59:07



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:11', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '20271991-23e4-435c-a97f-223998eee765' User entered 'None (0)'	System	23 Oct 2020 01:14:29
	System	23 Oct 2020 01:14:29

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '20271991-23e4-435c-a97f-223998eee765' User entered 'None (0)'	System	23 Oct 2020 01:14:29
	System	23 Oct 2020 01:14:29

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:16', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '20271991-23e4-435c-a97f-223998eee765' User entered 'None (0)'	System	23 Oct 2020 01:14:29
	System	23 Oct 2020 01:14:29

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:11:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:18', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '20271991-23e4-435c-a97f-223998eee765' User entered 'None (0)'	System	23 Oct 2020 01:14:29
	System	23 Oct 2020 01:14:29

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:20', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '20271991-23e4-435c-a97f-223998eee765' User entered 'None (0)'	System	23 Oct 2020 01:14:29
	System	23 Oct 2020 01:14:29

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:22', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '20271991-23e4-435c-a97f-223998eee765' User entered 'None (0)'	System	23 Oct 2020 01:14:29
	System	23 Oct 2020 01:14:29

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:25', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '20271991-23e4-435c-a97f-223998eee765' User entered 'No (N)'	System	23 Oct 2020 01:14:29
	System	23 Oct 2020 01:14:29

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-22T21:14:28', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '20271991-23e4-435c-a97f-223998eee765' User entered '22 Oct 2020 21:14'	System	23 Oct 2020 01:14:29
	System	23 Oct 2020 01:14:29



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 5'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:56', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '748b6a8d-993e-4d26-af0d-12261cf04b1f' User entered 'None (0)'	System	23 Oct 2020 20:58:23
	System	23 Oct 2020 20:58:23

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:57:58', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '748b6a8d-993e-4d26-af0d-12261cf04b1f' User entered 'None (0)'	System	23 Oct 2020 20:58:23
	System	23 Oct 2020 20:58:23

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:58:02', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '748b6a8d-993e-4d26-af0d-12261cf04b1f' User entered 'None (0)'	System	23 Oct 2020 20:58:23
	System	23 Oct 2020 20:58:23

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:58:06', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '748b6a8d-993e-4d26-af0d-12261cf04b1f' User entered 'None (0)'	System	23 Oct 2020 20:58:23
	System	23 Oct 2020 20:58:23

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:58:09', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '748b6a8d-993e-4d26-af0d-12261cf04b1f' User entered 'None (0)'	System	23 Oct 2020 20:58:23
	System	23 Oct 2020 20:58:23



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:58:11', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '748b6a8d-993e-4d26-af0d-12261cf04b1f' User entered 'None (0)'	System	23 Oct 2020 20:58:23
	System	23 Oct 2020 20:58:23

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:58:17', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '748b6a8d-993e-4d26-af0d-12261cf04b1f' User entered 'No (N)'	System	23 Oct 2020 20:58:23
	System	23 Oct 2020 20:58:23

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-23T16:58:20', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '748b6a8d-993e-4d26-af0d-12261cf04b1f' User entered '23 Oct 2020 16:58'	System	23 Oct 2020 20:58:23
	System	23 Oct 2020 20:58:23

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 6'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:20', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4d6ef5d5-b370-43fa-a84c-410fc737f312' User entered 'None (0)'	System	25 Oct 2020 01:31:43
	System	25 Oct 2020 01:31:43

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:22', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4d6ef5d5-b370-43fa-a84c-410fc737f312' User entered 'None (0)'	System	25 Oct 2020 01:31:43
	System	25 Oct 2020 01:31:43



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:25', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4d6ef5d5-b370-43fa-a84c-410fc737f312' User entered 'None (0)'	System	25 Oct 2020 01:31:43
	System	25 Oct 2020 01:31:43

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:27', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4d6ef5d5-b370-43fa-a84c-410fc737f312' User entered 'None (0)'	System	25 Oct 2020 01:31:43
	System	25 Oct 2020 01:31:43

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:29', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4d6ef5d5-b370-43fa-a84c-410fc737f312' User entered 'None (0)'	System	25 Oct 2020 01:31:43
	System	25 Oct 2020 01:31:43

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:31', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4d6ef5d5-b370-43fa-a84c-410fc737f312' User entered 'None (0)'	System	25 Oct 2020 01:31:43
	System	25 Oct 2020 01:31:43

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:34', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4d6ef5d5-b370-43fa-a84c-410fc737f312' User entered 'No (N)'	System	25 Oct 2020 01:31:43
	System	25 Oct 2020 01:31:43

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-24T21:31:38', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '4d6ef5d5-b370-43fa-a84c-410fc737f312'	System	25 Oct 2020 01:31:43
User entered '24 Oct 2020 21:31'	System	25 Oct 2020 01:31:43

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 19:59:07



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	19 Oct 2020 19:59:07
User entered 'Day 7'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:23:24', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b2c015ed-e0d1-4086-80d9-c73f95ba72f2'	System	26 Oct 2020 02:23:49
User entered 'No interference with activity (1)'	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:23:27', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b2c015ed-e0d1-4086-80d9-c73f95ba72f2' User entered 'None (0)'	System	26 Oct 2020 02:23:49
	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:23:30', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b2c015ed-e0d1-4086-80d9-c73f95ba72f2' User entered 'None (0)'	System	26 Oct 2020 02:23:49
	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:23:33', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b2c015ed-e0d1-4086-80d9-c73f95ba72f2' User entered 'None (0)'	System	26 Oct 2020 02:23:49
	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:23:35', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b2c015ed-e0d1-4086-80d9-c73f95ba72f2' User entered 'None (0)'	System	26 Oct 2020 02:23:49
	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:23:38', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b2c015ed-e0d1-4086-80d9-c73f95ba72f2' User entered 'None (0)'	System	26 Oct 2020 02:23:49
	System	26 Oct 2020 02:23:49

US3602074

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:23:42', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b2c015ed-e0d1-4086-80d9-c73f95ba72f2' User entered 'No (N)'	System	26 Oct 2020 02:23:49
	System	26 Oct 2020 02:23:49



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-25T22:23:44', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'b2c015ed-e0d1-4086-80d9-c73f95ba72f2' User entered '25 Oct 2020 22:23'	System	26 Oct 2020 02:23:49
	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 19:59:07

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	26 Oct 2020 02:23:49
User entered 'Day 8'	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:11:56**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-26T12:09:41', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a1538a53-e5b8-4f6a-98e4-e134d028610e' User entered 'None (0)'	System	26 Oct 2020 16:09:48
	System	26 Oct 2020 16:09:48

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-26T12:09:45', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a1538a53-e5b8-4f6a-98e4-e134d028610e' User entered '26 Oct 2020 12:09'	System	26 Oct 2020 16:09:48
	System	26 Oct 2020 16:09:48

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Oct 2020 12:00'	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '27 Oct 2020 11:59'	System	26 Oct 2020 02:23:49



**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
Data entry locked.	System	26 Oct 2020 02:23:49
User entered 'Day 8'	System	26 Oct 2020 02:23:49

US3602074

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-26T12:09:49', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '80f9c2fa-943b-4dcb-b52b-1e5a1c613561' User entered 'No (N)'	System	26 Oct 2020 16:09:53
	System	26 Oct 2020 16:09:53

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-10-26T12:09:52', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '80f9c2fa-943b-4dcb-b52b-1e5a1c613561' User entered '26 Oct 2020 12:09'	System	26 Oct 2020 16:09:53
	System	26 Oct 2020 16:09:53

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '26 Oct 2020 12:00'	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:11:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 02:13:54
User entered '27 Oct 2020 11:59'	System	26 Oct 2020 02:23:49

**US3602074**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:32

**US3602074**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:32

**US3602074**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:32



**US3602074**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:57:32

**US3602074**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 18:58:14

**US3602074**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	30 Oct 2020 18:58:14

**US3602074**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:24

**US3602074**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:24

**US3602074**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:24

**US3602074**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:24

**US3602074**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:39:29



**US3602074**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	17 Nov 2020 17:39:29

**US3602074**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:02

**US3602074**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:02

**US3602074**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:02

**US3602074**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:02

**US3602074**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:07

**US3602074**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	17 Nov 2020 17:40:07

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:24



**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:24

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:40:24

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'VISIT3'	System	17 Nov 2020 17:40:24

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '12:05'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '17 Nov 2020 12:05'	System	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11



**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '80'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'bpm'	System	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '18'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'breaths/min'	System	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '135'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	17 Nov 2020 17:41:11



**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '86'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'mmHg'	System	17 Nov 2020 17:41:11

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:20

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:20

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:31

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:31



**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered '12:05'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:31

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered '17 Nov 2020 12:05'	System	17 Nov 2020 17:41:31

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:41:36

**US3602074**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	17 Nov 2020 17:41:36

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-11-21T09:16:08', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '88a50c96-3c47-4359-aceb-a8a4a2d7b722'	System	21 Nov 2020 14:16:25
User entered 'No (N)'	System	21 Nov 2020 14:16:25

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-11-21T09:16:16', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '88a50c96-3c47-4359-aceb-a8a4a2d7b722'	System	21 Nov 2020 14:16:25
User entered 'No (N)'	System	21 Nov 2020 14:16:25

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-11-21T09:16:22', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '88a50c96-3c47-4359-aceb-a8a4a2d7b722'	System	21 Nov 2020 14:16:25
User entered '21 Nov 2020 09:16:22'	System	21 Nov 2020 14:16:25



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-11-27T00:01:05', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '1dbd3e04-a7ec-43b1-baf1-39876bbe6f1f' User entered 'No (N)'	System	27 Nov 2020 05:01:40
	System	27 Nov 2020 05:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-11-27T00:01:15', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '1dbd3e04-a7ec-43b1-baf1-39876bbe6f1f' User entered 'No (N)'	System	27 Nov 2020 05:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-11-27T00:01:27', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '1dbd3e04-a7ec-43b1-baf1-39876bbe6f1f' User entered '27 Nov 2020 00:01:27'	System	27 Nov 2020 05:01:40
	System	27 Nov 2020 05:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:29:58', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered 'Yes (Y)'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:05', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered 'No (N)'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:16', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered 'Yes (Y)'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c'	System	02 Dec 2020 14:31:10
User entered '1'	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c'	System	02 Dec 2020 14:31:10
User entered '1'	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '1'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '1'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '1'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c'	System	02 Dec 2020 14:31:10
User entered '0'	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '0'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:40', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c'	System	02 Dec 2020 14:31:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:49', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c'	System	02 Dec 2020 14:31:10
User entered 'Yes (Y)'	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:30:54', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c'	System	02 Dec 2020 14:31:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Dec 2020 14:31:10



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-02T09:31:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '41272f72-3db9-4696-b930-6ea35da2749c' User entered '02 Dec 2020 09:31:00'	System	02 Dec 2020 14:31:10
	System	02 Dec 2020 14:31:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:00:24', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered 'Yes (Y)'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:00:35', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered 'Yes (Y)'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:00:40', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:00:47', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered 'Yes (Y)'	System	11 Dec 2020 17:01:40



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '1'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '1'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '1'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '1'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '1'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '0'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '0'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '1'	System	11 Dec 2020 17:01:40



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '1'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '0'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '0'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '1'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '0'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '0'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '0'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '0'	System	11 Dec 2020 17:01:40



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered '0'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:16', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:24', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered 'Yes (Y)'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:26', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4'	System	11 Dec 2020 17:01:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-11T12:01:30', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ec7c56fa-a25e-4efa-b56a-ae41bf66b7b4' User entered '11 Dec 2020 12:01:30'	System	11 Dec 2020 17:01:40
	System	11 Dec 2020 17:01:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-16T11:40:31', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '6069c071-0609-4b17-b9b9-b3399cba18dd' User entered 'Yes (Y)'	System	16 Dec 2020 16:41:36
	System	16 Dec 2020 16:41:36

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-16T11:40:40', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '6069c071-0609-4b17-b9b9-b3399cba18dd'	System	16 Dec 2020 16:41:36
User entered 'Yes (Y)'	System	16 Dec 2020 16:41:36

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-16T11:40:46', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '6069c071-0609-4b17-b9b9-b3399cba18dd'	System	16 Dec 2020 16:41:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 16:41:36

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-16T11:40:54', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '6069c071-0609-4b17-b9b9-b3399cba18dd' User entered 'No (N)'	System	16 Dec 2020 16:41:36
	System	16 Dec 2020 16:41:36

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-16T11:41:11', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '6069c071-0609-4b17-b9b9-b3399cba18dd' User entered 'Yes (Y)'	System	16 Dec 2020 16:41:36
	System	16 Dec 2020 16:41:36

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-16T11:41:20', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '6069c071-0609-4b17-b9b9-b3399cba18dd'	System	16 Dec 2020 16:41:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 16:41:36

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1C21D590-E5DD-405C-A2C1-C8C9D620B772)', Time: '2020-12-16T11:41:24', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '6069c071-0609-4b17-b9b9-b3399cba18dd' User entered '16 Dec 2020 11:41:24'	System	16 Dec 2020 16:41:36
	System	16 Dec 2020 16:41:36

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-01T11:43:43', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'bd1f1393-7ec6-44e4-9eb1-51381646710e'	System	01 Jan 2021 16:44:08
User entered 'No (N)'	System	01 Jan 2021 16:44:08

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-01T11:43:53', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'bd1f1393-7ec6-44e4-9eb1-51381646710e'	System	01 Jan 2021 16:44:08
User entered 'No (N)'	System	01 Jan 2021 16:44:08

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-01T11:44:04', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'bd1f1393-7ec6-44e4-9eb1-51381646710e' User entered '01 Jan 2021 11:44:04'	System	01 Jan 2021 16:44:08
	System	01 Jan 2021 16:44:08



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-07T20:28:09', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e7994708-d891-451f-8e9f-9f156f37438e' User entered 'No (N)'	System	08 Jan 2021 01:28:20
	System	08 Jan 2021 01:28:20

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-07T20:28:13', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e7994708-d891-451f-8e9f-9f156f37438e' User entered 'No (N)'	System	08 Jan 2021 01:28:20

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-07T20:28:17', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'e7994708-d891-451f-8e9f-9f156f37438e' User entered '07 Jan 2021 20:28:17'	System	08 Jan 2021 01:28:20
	System	08 Jan 2021 01:28:20

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-13T11:21:26', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'fd584d9d-045c-4aef-8e8c-e49b2fcff0d6'	System	13 Jan 2021 16:21:39
User entered 'No (N)'	System	13 Jan 2021 16:21:39

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-13T11:21:33', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'fd584d9d-045c-4aef-8e8c-e49b2fcff0d6'	System	13 Jan 2021 16:21:39
User entered 'No (N)'	System	13 Jan 2021 16:21:39

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-13T11:21:35', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'fd584d9d-045c-4aef-8e8c-e49b2fcff0d6'	System	13 Jan 2021 16:21:39
User entered '13 Jan 2021 11:21:35'	System	13 Jan 2021 16:21:39

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-20T11:12:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '0b59b879-a29d-43e3-9249-d7b178c5e02f' User entered 'No (N)'	System	20 Jan 2021 16:12:57
	System	20 Jan 2021 16:12:57



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-20T11:12:50', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '0b59b879-a29d-43e3-9249-d7b178c5e02f'	System	20 Jan 2021 16:12:57
User entered 'No (N)'	System	20 Jan 2021 16:12:57

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-20T11:12:52', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '0b59b879-a29d-43e3-9249-d7b178c5e02f' User entered '20 Jan 2021 11:12:52'	System	20 Jan 2021 16:12:57

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-27T09:38:30', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8e272cb3-81b6-4baa-b40e-0dec71dacffa' User entered 'No (N)'	System	05 Feb 2021 00:34:18
	System	05 Feb 2021 00:34:18

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-27T09:38:37', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8e272cb3-81b6-4baa-b40e-0dec71dacffa' User entered 'No (N)'	System	05 Feb 2021 00:34:18

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-01-27T09:38:41', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '8e272cb3-81b6-4baa-b40e-0dec71dacffa' User entered '27 Jan 2021 09:38:41'	System	05 Feb 2021 00:34:18
	System	05 Feb 2021 00:34:18



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-04T19:34:23', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'd17fa121-578a-49e5-b466-78ed5c400503'	System	05 Feb 2021 00:34:40
User entered 'No (N)'	System	05 Feb 2021 00:34:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-04T19:34:34', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'd17fa121-578a-49e5-b466-78ed5c400503'	System	05 Feb 2021 00:34:40
User entered 'No (N)'	System	05 Feb 2021 00:34:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-04T19:34:38', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'd17fa121-578a-49e5-b466-78ed5c400503'	System	05 Feb 2021 00:34:40
User entered '04 Feb 2021 19:34:38'	System	05 Feb 2021 00:34:40

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-11T09:30:32', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2b7792f3-5e60-41e9-886c-70bef6967956'	System	11 Feb 2021 14:30:51
User entered 'No (N)'	System	11 Feb 2021 14:30:51

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-11T09:30:43', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2b7792f3-5e60-41e9-886c-70bef6967956'	System	11 Feb 2021 14:30:51
User entered 'No (N)'	System	11 Feb 2021 14:30:51

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-11T09:30:47', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '2b7792f3-5e60-41e9-886c-70bef6967956'	System	11 Feb 2021 14:30:51
User entered '11 Feb 2021 09:30:47'	System	11 Feb 2021 14:30:51

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-17T09:33:03', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '13e58848-4cbf-4970-a6e4-d0c002a393dd' User entered 'No (N)'	System	17 Feb 2021 14:33:29
	System	17 Feb 2021 14:33:29



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-17T09:33:23', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '13e58848-4cbf-4970-a6e4-d0c002a393dd'	System	17 Feb 2021 14:33:29
User entered 'No (N)'	System	17 Feb 2021 14:33:29

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-17T09:33:26', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '13e58848-4cbf-4970-a6e4-d0c002a393dd' User entered '17 Feb 2021 09:33:26'	System	17 Feb 2021 14:33:29
	System	17 Feb 2021 14:33:29

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-24T14:03:10-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '074bd914-d19c-405e-b1fe-6404d429f48a' User entered 'No (N)'	System	24 Feb 2021 19:03:27
	System	24 Feb 2021 19:03:27

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-24T14:03:14-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '074bd914-d19c-405e-b1fe-6404d429f48a' User entered 'No (N)'	System	24 Feb 2021 19:03:27
	System	24 Feb 2021 19:03:27

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-24T14:03:20-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '074bd914-d19c-405e-b1fe-6404d429f48a' User entered '24 Feb 2021 19:03:20'	System	24 Feb 2021 19:03:27
	System	24 Feb 2021 19:03:27



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-03T08:29:48-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cef30d1b-cdc3-4919-ad21-5c9b4e815a82'	System	03 Mar 2021 13:30:06
User entered 'No (N)'	System	03 Mar 2021 13:30:06

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-03T08:29:57-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cef30d1b-cdc3-4919-ad21-5c9b4e815a82'	System	03 Mar 2021 13:30:06
User entered 'No (N)'	System	03 Mar 2021 13:30:06

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-03T08:30:01-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'cef30d1b-cdc3-4919-ad21-5c9b4e815a82'	System	03 Mar 2021 13:30:06
User entered '03 Mar 2021 08:30:01'	System	03 Mar 2021 13:30:06

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-10T09:38:36-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '372aa7a1-3c3a-470c-9e2e-4d67b39c11fb'	System	10 Mar 2021 14:39:10
User entered 'No (N)'	System	10 Mar 2021 14:39:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-10T09:38:48-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '372aa7a1-3c3a-470c-9e2e-4d67b39c11fb'	System	10 Mar 2021 14:39:10
User entered 'No (N)'	System	10 Mar 2021 14:39:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-10T09:38:52-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '372aa7a1-3c3a-470c-9e2e-4d67b39c11fb' User entered '10 Mar 2021 09:38:52'	System	10 Mar 2021 14:39:10
	System	10 Mar 2021 14:39:10

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-17T13:15:18-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a3520722-7b38-4b87-bbcc-9efb2cf12eae'	System	17 Mar 2021 17:15:52
User entered 'No (N)'	System	17 Mar 2021 17:15:52



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-17T13:15:24-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a3520722-7b38-4b87-bbcc-9efb2cf12eae'	System	17 Mar 2021 17:15:52
User entered 'No (N)'	System	17 Mar 2021 17:15:52

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-17T13:15:28-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'a3520722-7b38-4b87-bbcc-9efb2cf12eae'	System	17 Mar 2021 17:15:52
User entered '17 Mar 2021 13:15:28'	System	17 Mar 2021 17:15:52

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-25T09:55:31-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f5631013-777b-4d7a-9406-9401b120bd3e'	System	25 Mar 2021 13:55:49
User entered 'No (N)'	System	25 Mar 2021 13:55:49

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-25T09:55:42-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f5631013-777b-4d7a-9406-9401b120bd3e'	System	25 Mar 2021 13:55:49
User entered 'No (N)'	System	25 Mar 2021 13:55:49

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-25T09:55:46-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'f5631013-777b-4d7a-9406-9401b120bd3e'	System	25 Mar 2021 13:55:49
User entered '25 Mar 2021 09:55:46'	System	25 Mar 2021 13:55:49



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-31T07:41:20-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '3e1a6381-3938-4ee8-ba68-383600d6b5ad'	System	31 Mar 2021 11:41:39
User entered 'No (N)'	System	31 Mar 2021 11:41:39

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-31T07:41:31-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '3e1a6381-3938-4ee8-ba68-383600d6b5ad'	System	31 Mar 2021 11:41:39
User entered 'No (N)'	System	31 Mar 2021 11:41:39

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-03-31T07:41:36-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '3e1a6381-3938-4ee8-ba68-383600d6b5ad' User entered '31 Mar 2021 07:41:36'	System	31 Mar 2021 11:41:39
	System	31 Mar 2021 11:41:39

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-08T07:32:47-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'd88f0480-8376-4651-964a-1779f24d6b1b'	System	09 Apr 2021 21:46:49
User entered 'No (N)'	System	09 Apr 2021 21:46:49

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-08T07:32:56-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'd88f0480-8376-4651-964a-1779f24d6b1b'	System	09 Apr 2021 21:46:49
User entered 'No (N)'	System	09 Apr 2021 21:46:49

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-08T07:33:01-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'd88f0480-8376-4651-964a-1779f24d6b1b'	System	09 Apr 2021 21:46:49
User entered '08 Apr 2021 07:33:01'	System	09 Apr 2021 21:46:49

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-14T07:55:18-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ee807e26-93df-4c8a-b052-76a18a291acb'	System	14 Apr 2021 13:14:30
User entered 'No (N)'	System	14 Apr 2021 13:14:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-14T07:55:33-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ee807e26-93df-4c8a-b052-76a18a291acb'	System	14 Apr 2021 13:14:30
User entered 'No (N)'	System	14 Apr 2021 13:14:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-14T07:55:36-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: 'ee807e26-93df-4c8a-b052-76a18a291acb'	System	14 Apr 2021 13:14:30
User entered '14 Apr 2021 07:55:36'	System	14 Apr 2021 13:14:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-22T20:21:58-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66a3623e-e990-4292-aca1-5dcd51d8d065'	System	23 Apr 2021 00:22:07
User entered 'No (N)'	System	23 Apr 2021 00:22:07

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-22T20:22:00-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66a3623e-e990-4292-aca1-5dcd51d8d065'	System	23 Apr 2021 00:22:07
User entered 'No (N)'	System	23 Apr 2021 00:22:07

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-22T20:22:03-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66a3623e-e990-4292-aca1-5dcd51d8d065'	System	23 Apr 2021 00:22:07
User entered '22 Apr 2021 20:22:03'	System	23 Apr 2021 00:22:07



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-28T08:05:44-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9f1e4a8b-8426-4842-8988-73f2ea41e02c'	System	28 Apr 2021 23:17:20
User entered 'No (N)'	System	28 Apr 2021 23:17:20

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-28T08:05:47-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9f1e4a8b-8426-4842-8988-73f2ea41e02c'	System	28 Apr 2021 23:17:20
User entered 'No (N)'	System	28 Apr 2021 23:17:20

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-04-28T08:05:50-04:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '9f1e4a8b-8426-4842-8988-73f2ea41e02c'	System	28 Apr 2021 23:17:20
User entered '28 Apr 2021 08:05:50'	System	28 Apr 2021 23:17:20

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 09:59:30



**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 09:59:30

**US3602074**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:11:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:59:30
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 09:59:30

US3602074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:11:56

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:14:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-27T10:32:49-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66359d05-c9aa-4111-913b-74d0d84bd4bd' User entered 'No (N)'	System	27 Feb 2021 15:32:56

**US3602074**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:14:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (121B503F-80F4-49BC-A2EE-082893C95290)', Time: '2021-02-27T10:32:54-05:00', User OID: 'PatientReportedOutcome (US3602074)', ODM File OID: '66359d05-c9aa-4111-913b-74d0d84bd4bd' User entered '27 Feb 2021 15:32:54'	System	27 Feb 2021 15:32:56
	System	27 Feb 2021 15:32:56



**US3602074**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:21:54

**US3602074**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:21:54

**US3602074**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:21:54

**US3602074**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
Signature has been broken.	(b) (4), (b) (6)	24 Mar 2021 15:55:39
User entered 'Subject was on convalescent phase during this time. As per protocol, no contact was made with subject for scheduled safety call.' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 15:55:39
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Dec 2020 19:21:54

**US3602074**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:22:08

**US3602074**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:37:29
User entered 'I'	System	15 Dec 2020 19:22:08

**US3602074**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:33:51

**US3602074**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:33:51



**US3602074**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:33:51

**US3602074**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:33:51

**US3602074**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:33:57

**US3602074**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User entered 'I'	System	20 Jan 2021 00:33:57

US3602074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	24 Feb 2021 15:22:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 15:22:40
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	24 Feb 2021 15:22:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 15:22:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 15:13:47

US3602074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) System	24 Feb 2021 15:22:35
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	24 Feb 2021 15:22:35
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 15:22:35
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	24 Feb 2021 15:13:47
User entered '22 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 15:13:47

**US3602074**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:13:47

**US3602074**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Combined with OL Visit Day 29 on 02/22/2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:13:47



**US3602074**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:23:41

**US3602074**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User entered 'I'	System	24 Feb 2021 15:23:41

**US3602074**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Yes (Y)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:51:29
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	24 Mar 2021 02:17:39
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	24 Mar 2021 02:17:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 02:17:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 02:12:02

US3602074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '21 Mar 2021' reason for change: New Information	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:51:29
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Mar 2021 02:17:03
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	24 Mar 2021 02:17:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 02:17:03
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Mar 2021 02:13:40
User entered '12 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 02:13:40
User entered '18 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 02:12:02

**US3602074**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:51:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 02:17:39
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 02:17:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Mar 2021 02:12:02

US3602074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:11:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered empty; reason for change New Information	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 15:51:29
User entered 'SUBJECT VISITED STUDY SITE ON 12/MARCH/21 FOR DAY 57V3OL. THIS VISIT WAS THOUGHT TO HAVE OVERLAPPED WITH DAY 179 SC, HOWEVER IT WAS STILL OUT OF WINDOW AND WAS NOT DONE.'	(b) (4), (b) (6)	24 Mar 2021 15:58:09
reason for change: New Information		
User entered 'SUBJECT VISITED STUDY SITE ON 12/MARCH/21 FOR DAY 57V3OL. THIS VISIT OVERLAPS WITH DAY 179 SC.'	(b) (4), (b) (6)	24 Mar 2021 02:17:03
reason for change: Data Entry Error		
User entered 'Please not subject visited study site on 12/March/21 for day 57V3OL. This visit overlaps with day 179 SC. Will continue to follow appropriately.'	(b) (4), (b) (6)	24 Mar 2021 02:13:40
reason for change: Data Entry Error		
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 02:12:02

**US3602074**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 02:12:42

**US3602074**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:38:31
User entered 'I'	System	24 Mar 2021 02:12:42



**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:24:57

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:24:57

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:24:57

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	16 Apr 2021 19:24:57

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '12:00'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User entered '15 Apr 2021 12:00'	System	16 Apr 2021 19:28:42



**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '87'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '18'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '123'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42



**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '88'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 19:28:42

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:07

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:07

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:21

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:21

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered '12:18'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:25:21



**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User entered '15 Apr 2021 12:18'	System	16 Apr 2021 19:25:21

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:29:31

**US3602074**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 19:29:31

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:56

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (29Nov 2020). Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 04:31:27
Query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (29Nov 2020). Please review and reconcile.' answered with 'Date of Contact is 11/29/2020 and date of symptom log started on 11/29/2020.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 17:20:23
User opened query 'Per CDM: It appears that both initial start date of symptoms and Contact date are the same (29Nov 2020). Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 21:01:52
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 03:21:42
User closed query 'Re-query: Please reconcile and enter severity page as required. Please leave query open and do not respond until severity information is available.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:21:40
Query 'Re-query: Please reconcile and enter severity page as required. Please leave query open and do not respond until severity information is available.' answered with 'Info was documented in EMR as of today 1/4/2021. Transcribed onto Medidata per source.' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 20:48:52
User opened query 'Re-query: Please reconcile and enter severity page as required. Please leave query open and do not respond until severity information is available.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:43:45
User closed query 'Please reconcile and enter severity page as required.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:43:45
Query 'Please reconcile and enter severity page as required.' answered with 'Unable to provide severity assessment information as of today, subject is still hospitalized. Will update when information becomes available. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 19:17:32
User opened query 'Please reconcile and enter severity page as required.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:31:33

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:56

[Date of Contact](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample:Re-Query:Thank you for your response, however, SARS-COV-2 serum sample dated 02 DEC 2020 is still missing in EDC, and EDC has provision to enter this SARS serum sample data, only under Illness visit folder under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form. Please kindly update this SARS-COV-2 Sample data , under Illness visit folder, as per CCV2.0 pg 16. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 09:45:28
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample:Re-Query:Thank you for your response, however, SARS-COV-2 serum sample dated 02 DEC 2020 is still missing in EDC, and EDC has provision to enter this SARS serum sample data, only under Illness visit folder under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form. Please kindly update this SARS-COV-2 Sample data , under Illness visit folder, as per CCV2.0 pg 16. Thank you.' answered with 'Updated blood sample info inserted' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 16:51:00
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample:Re-Query:Thank you for your response, however, SARS-COV-2 serum sample dated 02 DEC 2020 is still missing in EDC, and EDC has provision to enter this SARS serum sample data, only under Illness visit folder under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection form. Please kindly update this SARS-COV-2 Sample data , under Illness visit folder, as per CCV2.0 pg 16. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 12:53:59
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 02-DEC-2020 under Illness Visit Day 1; however, there is no record in EDC. Please confirm the correct visit and update EDC. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 12:53:01

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:56

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Thank you for your response, as per CCGv.2.0 pg 16, Please create Covid-19 Illness Visit generated by using the 'Add Events' tool located on the patient's main page, as the provision for entering SARS serum sample collection data is provided in EDC only under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection page, please enter the details for SARS serum Sample dated 02 DEC 2020 under it, as it is still missing under EDC, and reported under illness Visit Day 1 in PPD Central lab. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 12:52:22
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Thank you for your response, as per CCGv.2.0 pg 16, Please create Covid-19 Illness Visit generated by using the 'Add Events' tool located on the patient's main page, as the provision for entering SARS serum sample collection data is provided in EDC only under Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection page, please enter the details for SARS serum Sample dated 02 DEC 2020 under it, as it is still missing under EDC, and reported under illness Visit Day 1 in PPD Central lab. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 04:07:59
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 04:07:59

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Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:56

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' answered with 'Sample was collected. Covid Dx Test folder updated' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 19:10:39
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 02-DEC-2020 under Illness Visit Day 1; however, there is no record in EDC. Please confirm the correct visit and update EDC. Else clarify, thank you.' answered with 'N.P Swab info updated' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 19:09:33
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab1: It appears PPD Central Lab has a Nasopharyngeal Swab Sample with date 02-DEC-2020 under Illness Visit Day 1; however, there is no record in EDC. Please confirm the correct visit and update EDC. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:13:45
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 06:56:18
User entered '29 Nov 2020'	(b) (4), (b) (6)	03 Dec 2020 14:38:14

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**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:11:56**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:40:10
User entered '08:15'	(b) (4), (b) (6)	03 Dec 2020 14:38:14



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:11:56**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:35
User entered '29 Nov 2020 08:15'	System	03 Dec 2020 14:38:14

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Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:11:56

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:43:24
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 03:41:51
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:40:12
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:30:29
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	03 Dec 2020 14:38:14

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**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:11:56**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:35
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:43:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 14:38:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '29 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	04 Dec 2020 23:32:58



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
User closed query 'Per CDM: It appears data is missing for days 1 - 11. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 09:21:00
Query 'Per CDM: It appears data is missing for days 1 - 11. Please review and update accordingly.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 17:34:59
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User opened query 'Per CDM: It appears data is missing for days 1 - 11. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 21:04:13
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:32:58



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Dec 2020 23:32:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '30 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:11:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Dec 2020 23:33:32

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:34:52



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '1 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered missing code ND - Not Done; reason for change New Information	(b) (4), (b) (6)	04 Dec 2020 23:54:35
User entered empty; reason for change New Information	(b) (4), (b) (6)	04 Dec 2020 23:54:25
User entered '99' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:51:24
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	04 Dec 2020 23:54:35
User entered empty.	System	04 Dec 2020 23:54:25
User entered '%'	System	04 Dec 2020 23:51:24
User entered empty.	System	04 Dec 2020 23:34:52

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:34:24
User closed query 'Progress notes, on the chart fever is recorded as starting 12/1/20 at 1900 with moderate severity. There was no temperature recorded. Please verify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 18:33:56
Query 'Progress notes, on the chart fever is recorded as starting 12/1/20 at 1900 with moderate severity. There was no temperature recorded. Please verify data and update accordingly.' answered with 'Temperature updated.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 18:31:08
User entered '102.0' F reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 18:30:40
User opened query 'Progress notes, on the chart fever is recorded as starting 12/1/20 at 1900 with moderate severity. There was no temperature recorded. Please verify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 17:29:50
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:06:24
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered missing code ND - Not Done; reason for change New Information	(b) (4), (b) (6)	04 Dec 2020 23:54:35
User entered empty; reason for change New Information	(b) (4), (b) (6)	04 Dec 2020 23:54:25
User entered '101' F reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:51:24
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:53:30
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:52:46
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:36:46
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 17:06:20
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 17:06:14
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty; reason for change New Information	(b) (4), (b) (6)	04 Dec 2020 23:53:30
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:52:46
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:56

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:11:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	04 Dec 2020 23:34:52

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '2 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:36:46



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '96' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:39:30
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	04 Dec 2020 23:39:30
User entered empty.	System	04 Dec 2020 23:36:46

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:56

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
User closed query 'Progress note at illness visit temperature recorded was 98.9. AE section of progress notes for Fever "102.8 as highest temperature recorded on 12/2/20." End time 1000 99.7 Temp is recorded. Please verify temperature and update data if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 02:19:19
Query 'Progress note at illness visit temperature recorded was 98.9. AE section of progress notes for Fever "102.8 as highest temperature recorded on 12/2/20." End time 1000 99.7 Temp is recorded. Please verify temperature and update data if necessary.' answered with 'Temperature is correct. Data clarification added on 01/21/2021 in source.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 17:12:49
User opened query 'Progress note at illness visit temperature recorded was 98.9. AE section of progress notes for Fever "102.8 as highest temperature recorded on 12/2/20." End time 1000 99.7 Temp is recorded. Please verify temperature and update data if necessary.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:07:40
Query 'Per progress note on 12/2/20, under AEs, Fever is recorded as 102.8 as highest temperature recorded on 12/2/20. Please verify temperature and update data if necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:01:22
User opened query 'Per progress note on 12/2/20, under AEs, Fever is recorded as 102.8 as highest temperature recorded on 12/2/20. Please verify temperature and update data if necessary.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 18:43:04
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 18:40:14
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '98.9' F reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:39:30
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Moderate (Moderate)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:39:30
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:24
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:28
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:30
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:39:30
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:33
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:35
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:37
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:39
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:42
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:56

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:45
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:46
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46



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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:11:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:19:50
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:39:30
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:36:46

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '3 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '99' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:56:48
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	04 Dec 2020 23:56:48
User entered empty.	System	04 Dec 2020 23:54:25



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '101' F reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:56:48
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:56:48
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:14
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:15
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:17
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:56:48
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:20
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:23
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:56:48
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:26
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:30
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:34
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:36
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:42
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:44
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:20:45
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:56:48
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:54:25

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '4 Dec 2020'	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '97'	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '99' F	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	08 Dec 2020 22:11:19



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:56

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Dec 2020 22:11:19

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:11:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	08 Dec 2020 22:11:19

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:05:24



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '5 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:08
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:53:33
User entered '0' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:53:33
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '1'	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:13
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:45:43
User entered missing code ND - Not Done; reason for change New Information	(b) (4), (b) (6)	06 Jan 2021 20:45:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	06 Jan 2021 20:45:43
User entered empty.	System	10 Dec 2020 16:05:24

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:59:19
User closed query 'On encounter day dated 12/6/20, the chart has data for 12/5/20. Please verify and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 20:58:56
Query 'On encounter day dated 12/6/20, the chart has data for 12/5/20. Please verify and update data accordingly.' answered with 'Verified and updated data for 12/5/20.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 20:53:03
User entered '102.2' F reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:45:43
User opened query 'On encounter day dated 12/6/20, the chart has data for 12/5/20. Please verify and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 20:18:52
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:15:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:35
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:47:41
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:43:44
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:38
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:47:41
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:43:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:39
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:47:41
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:43:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:07
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:47:41
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:43:50
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:09
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:47:41
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:47:41
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:11
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:47:41
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:47:41
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:22
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:25
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'Mild (Mild)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:28
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:45
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:47
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:52
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:55
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:57
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:11:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:58
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:52:37
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 20:52:37
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:05:24

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '6 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 16:07:30



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '99' F	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:07:30

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:07:30



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:44:19
User closed query 'Per progress notes, HA is moderate. Please verify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 03:44:18
Query 'Per progress notes, HA is moderate. Please verify data and update accordingly.' answered with 'Updated.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:07:15
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 22:07:03
User opened query 'Per progress notes, HA is moderate. Please verify data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 21:27:52
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 21:27:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 16:07:30

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '7 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '95'	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	10 Dec 2020 16:42:14



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '99.9' F	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:42:14

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:42:14



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:42:14

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:42:14

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:11:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:42:14



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 16:42:14

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '8 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '95'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '101' F	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:45:01



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:45:01



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Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 16:45:01

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:45:01

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:45:01

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:45:01

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:11:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 16:45:01

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User closed query 'Per CDM: RQ: Response noted. Please add additional lines for Day 12,Day 13 and Day 14 to record symptoms or mark as assessment not done. Thank you ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 03:31:35
Query 'Per CDM: RQ: Response noted. Please add additional lines for Day 12,Day 13 and Day 14 to record symptoms or mark as assessment not done. Thank you ' answered with 'Day 12, 13, and 14 have been added to Symptom Log and completed as per query.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:09:40
User opened query 'Per CDM: RQ: Response noted. Please add additional lines for Day 12,Day 13 and Day 14 to record symptoms or mark as assessment not done. Thank you ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:42:40
User closed query 'Per CDM, per sponsor review: According to protocol, participants will be monitored by the study investigator for a 14-day period after diagnosis. Please review and, if applicable, add additional lines to record symptoms or mark as assessment not done. Else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:42:40
Query 'Per CDM, per sponsor review: According to protocol, participants will be monitored by the study investigator for a 14-day period after diagnosis. Please review and, if applicable, add additional lines to record symptoms or mark as assessment not done. Else clarify.' answered with 'Daily Illness Visit Day Follow-up Call & Symptom Severity Assessment stopped at Day 11/Dec. 9th, 2020 because subject ended up in the ER on Dec. 10th, 2021 and site was unable to contact subject for further symptom days. Please advise if Day 12, Day 13 and Day 14 should still be added and marked off as not done. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 14:01:31
User opened query 'Per CDM, per sponsor review: According to protocol, participants will be monitored by the study investigator for a 14-day period after diagnosis. Please review and, if applicable, add additional lines to record symptoms or mark as assessment not done. Else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:00:27



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '9 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered '94'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	10 Dec 2020 18:01:20

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Dec 2020 18:01:35
User entered '100' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 18:01:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Dec 2020 18:01:20
User entered '100' (non-conformant).	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 18:01:20

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 18:01:20



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 18:01:20

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 18:01:20

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:11:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:21:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:34:11
User entered 'None (None)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:34:11
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:53:40
User entered 'None (None)'	(b) (4), (b) (6)	10 Dec 2020 18:01:20

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:03:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered '10 Dec 2020'	(b) (4), (b) (6)	16 Apr 2021 13:03:58



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User closed query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 29 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:14:44
Query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 29 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Data has been deleted for all 17 symptoms.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:12:14
User opened query 'Per CDM: Please verify that Symptom Log Line 12 in Covid-19 Assessment 29 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:19:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:00:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:11:45
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 13:03:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	20 Apr 2021 13:11:45
User entered empty.	System	20 Apr 2021 13:06:25
User entered '%'	System	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:00:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:11:45
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:02
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:23
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:19
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:05
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:07
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:08
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:10
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:13
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:14
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:16
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:20
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:21
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:24
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:25
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:27
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:28
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:11:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:30
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:06:25
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:03:58

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:05:49

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered '11 Dec 2020'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User closed query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 29 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:15:47
Query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 29 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Data has been deleted for all 17 symptoms.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:15:45
User opened query 'Per CDM: Please verify that Symptom Log Line 13 in Covid-19 Assessment 29 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:19:18
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 13:05:49



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	16 Apr 2021 13:05:49

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:47
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:54
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:56
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:06:58
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:00
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:02
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:04
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:06
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:07
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:10
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:12
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:15
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:17
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:11:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:19
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:14:52
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:05:49

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:07:57

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered '12 Dec 2020'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User closed query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 29 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:18:25
Query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 29 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'Data for all 17 symptoms has been deleted.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:20:47
User opened query 'Per CDM: Please verify that Symptom Log Line 14 in Covid-19 Assessment 29 Nov 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:19:57
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 13:07:57

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:11:56**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User entered '%'	System	16 Apr 2021 13:07:57

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Symptom Log (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Apr 2021 13:07:57



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:34
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:36
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:37
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:39
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:42
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:52
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:53
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:54
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:11:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:06:54
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:07:59
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 13:20:01
User signature succeeded.	Bindu Balani (b) (4)	19 Apr 2021 01:12:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:46:18
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	16 Apr 2021 13:07:57



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:03
User entered '2 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 18:27:00

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:11:56**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 18:27:00

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:56

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:07
User closed query 'Per CDM: Kindly update the AE form for COVID-19 Diagnosis. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 03:29:57
Query 'Per CDM: Kindly update the AE form for COVID-19 Diagnosis. Thank you.' answered with 'Form updated. A.E documented per EMR' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 19:25:27
User opened query 'Per CDM: Kindly update the AE form for COVID-19 Diagnosis. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 05:04:04
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)	11 Dec 2020 05:01:59
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'A.E will be inserted. Request for provider to update EMR in progress' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 19:07:27
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	10 Dec 2020 18:27:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 18:27:00

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:56

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:11
User closed query 'Please verify as central lab notes collection date of 02Dec2020' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:42:47
Query 'Please verify as central lab notes collection date of 02Dec2020' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 17:04:54
User entered '2 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:04:29
User opened query 'Please verify as central lab notes collection date of 02Dec2020' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:30:35
User entered '4 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 18:27:00

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:11:56**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	10 Dec 2020 18:27:00

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:11:56**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:21
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 18:27:00

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:56

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:24
User closed query 'Please reconcile as this should be NO as the sample was performed at the central lab' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:42:49
Query 'Please reconcile as this should be NO as the sample was performed at the central lab' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 17:04:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:04:29
User opened query 'Please reconcile as this should be NO as the sample was performed at the central lab' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:30:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 18:27:00

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:56

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:28
User closed query 'Please remove data as it is not applicable if the central lab was used.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:42:50
Query 'Please remove data as it is not applicable if the central lab was used.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 17:04:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:04:29
User opened query 'Please remove data as it is not applicable if the central lab was used.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:31:10
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Dec 2020 19:08:04
User entered 'Moderna' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 19:08:04
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Dec 2020 18:27:00
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 18:27:00



US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:11:56

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:09:30
User closed query 'Please remove data as it is not applicable if the central lab was used.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:42:51
Query 'Please remove data as it is not applicable if the central lab was used.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 17:04:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 17:04:29
User opened query 'Please remove data as it is not applicable if the central lab was used.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 23:31:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 18:27:00

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:11:56**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:03
User entered 'I'	System	10 Dec 2020 18:27:00

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Did the subject have Respiratory Rates  \$\geq\$  30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:56

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 14:48:54
User closed query 'Please clear field as this doesn't meet criteria for severity noted.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 14:48:51
Query 'Please clear field as this doesn't meet criteria for severity noted.' answered with 'Field cleared per query resolution.' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 22:37:42
DataPoint Un-verified.	(b) (4), (b) (6)	15 Jan 2021 22:37:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 22:37:28
User opened query 'Please clear field as this doesn't meet criteria for severity noted.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:20:02
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered '28'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Did the subject have Heart Rate  \$\geq\$  125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

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Folder: Covid-19 Assessment 29 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:56

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Query 'Please verify as symptom log stopped on 09Dec2020' canceled (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 03:21:12
User opened query 'Please verify as symptom log stopped on 09Dec2020' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 03:20:36
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered '10 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:56

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:37:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 20:09:07
User closed query 'Per CDM, per sponsor review: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 17:45:00
Query 'Per CDM, per sponsor review: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. Else clarify. ' answered with 'End date updated per source. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 17:47:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:46:11
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 17:46:11
User entered '10 Dec 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Apr 2021 17:46:11
User opened query 'Per CDM, per sponsor review: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing. Please review and reconcile. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:56:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

US3602074

Folder: Covid-19 Assessment 29 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:11:56

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:15:16
User closed query 'Per CDM: Please review and confirm if the Oxygen Saturation data is available. Per the symptom log, O2 was 'not done' on 10DEC2020. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:10:24
Query 'Per CDM: Please review and confirm if the Oxygen Saturation data is available. Per the symptom log, O2 was 'not done' on 10DEC2020. ' answered with 'Entry updated per source.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 13:05:12
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 13:04:42
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 13:04:42
User entered '83' reason for change: Per Query Resolution	(b) (4), (b) (6)	21 Apr 2021 13:04:42
User opened query 'Per CDM: Please review and confirm if the Oxygen Saturation data is available. Per the symptom log, O2 was 'not done' on 10DEC2020. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:09:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

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**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered '10 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered '11 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 20:47:27



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered '19 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

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**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

**Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

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**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

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**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered '10 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 20:47:27



**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered '10 Dec 2020'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered 'No (N)'	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Covid-19 Severity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:07:15
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 03:47:17
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 20:47:27

**US3602074**

**Folder: Covid-19 Assessment 29 Nov 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:08:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:54:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:41:18

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 19:06:09



**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:41
User entered '4 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:39:35
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 21:05:34
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:45:45
User entered '06 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	16 Dec 2020 20:03:15
User entered '9 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:56:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 20:04:31
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:06:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 19:06:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 19:06:26
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:06:09
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:56:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '8 Dec 2020' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 20:04:31
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	10 Dec 2020 19:06:09



**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:57:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	10 Dec 2020 19:06:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 19:06:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 19:06:26
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:06:09
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:57:00
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:57:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 19:06:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 19:06:26
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:06:09
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 21:57:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	10 Dec 2020 19:06:09

US3602074

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:11:56

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Please confirm if Day 21 Illness visit call was completed? If yes, please complete eCRF accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 02:29:11
Query 'Please confirm if Day 21 Illness visit call was completed? If yes, please complete eCRF accordingly.' answered with 'Subject was contacted for his saliva on day 21 (not an illness follow up call), and then came in for day 28 per (b) (6)' (Site from CRA).	(b) (4), (b) (6)	12 Jan 2021 18:14:00
User opened query 'Please confirm if Day 21 Illness visit call was completed? If yes, please complete eCRF accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 04:43:33
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 04:30:02
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	29 Dec 2020 16:17:36
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:06:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 19:06:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 19:06:26
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:06:09
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:30:02
User entered '23 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	29 Dec 2020 16:17:36
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:06:09



**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:32:42
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:20:09
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:06:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 19:06:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Dec 2020 19:06:26
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 19:06:09
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:32:42
User entered '30 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:20:02
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:06:09

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 19:52:28

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:58:24
User entered '2 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 19:52:28

US3602074

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:03
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:57:32
User closed query 'Progress note has this was a Televisit. Please clarify and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:57:30
Query 'Progress note has this was a Televisit. Please clarify and update data accordingly.' answered with 'Updated.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 13:59:30
User entered 'Clinic (Clinic)' reason for change: Per Query Resolution	(b) (4), (b) (6)	07 Jan 2021 13:59:25
User opened query 'Progress note has this was a Televisit. Please clarify and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:15:02
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:14:28
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:00
User entered 'Home (Home)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 19:53:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Dec 2020 19:52:28

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:03
User entered 'SICKD1'	System	16 Dec 2020 19:52:28

US3602074

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:46
User closed query 'Progress notes recorded for encounter Day 12/2/20 has data. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:08:44
Query 'Progress notes recorded for encounter Day 12/2/20 has data. Please confirm data and update accordingly.' answered with 'Updated per EMR.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 14:02:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
User opened query 'Progress notes recorded for encounter Day 12/2/20 has data. Please confirm data and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:20:30
Query 'If this was a home visit, please clarify if assessments were completed.' canceled (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:19:02
User opened query 'If this was a home visit, please clarify if assessments were completed.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:15:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:15:08
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:32
User entered 'No (N)'	(b) (4), (b) (6)	16 Dec 2020 19:52:53



**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:07:59
User entered '2 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:07
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:35
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:01
User entered '12:11' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:09
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:36
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User entered '2 Dec 2020 12:11'	System	07 Jan 2021 14:02:05
User entered empty.	System	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:11
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:12
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:38
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53
DataPoint set to visible.	System	16 Dec 2020 19:52:28

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:09
User entered missing code ND - Not Done; reason for	(b) (4), (b) (6)	07 Jan 2021 14:02:05
change Data Entry Error		
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:14
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:41
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53
DataPoint set to visible.	System	16 Dec 2020 19:52:28

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:08
User entered '98.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:15
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:43
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:18
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:17
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:45
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:27
User entered 'Temporal/Forehead scanner was used' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:21
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:46
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53



**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:29
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:20
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:47
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User entered 'bpm'	System	07 Jan 2021 14:02:05
User entered empty.	System	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:35
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:24
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:49
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User entered 'breaths/min'	System	07 Jan 2021 14:02:05
User entered empty.	System	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:39
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:51
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User entered 'mmHg'	System	07 Jan 2021 14:02:05
User entered empty.	System	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:08:41
User entered '75' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 14:02:05
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 00:19:26
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:58:52
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:52:53

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07
User entered 'mmHg'	System	07 Jan 2021 14:02:05
User entered empty.	System	16 Dec 2020 19:52:53



**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:07

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:41
User entered 'No (N)'	(b) (4), (b) (6)	16 Dec 2020 19:53:46

**US3602074**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:43
User entered empty.	(b) (4), (b) (6)	16 Dec 2020 19:53:46

**US3602074**

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 10 Jun 2021 09:11:56**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:19
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Dec 2020 20:10:00

**US3602074**

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 10 Jun 2021 09:11:56**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:05:19
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:39:50
User entered '2 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	16 Dec 2020 20:56:36
User entered '3 Dec 2020'	(b) (4), (b) (6)	16 Dec 2020 20:10:00

US3602074

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:11:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:32:31
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:16:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 09:06:51
Query 'Data is required. Please complete.' answered with 'Data inserted in error' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 20:08:15
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 20:08:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:08:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 16:47:26

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:32:31
User entered '30 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:08:02
User entered '2 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 16:47:26



**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:32:31
User entered 'Clinic (Clinic)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:08:02
User entered 'Home (Home)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 16:48:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Dec 2020 16:47:26

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:05
User entered 'SICKD28'	System	30 Dec 2020 23:16:45
User entered empty.	System	16 Dec 2020 20:08:02
User entered 'SICKD28'	System	11 Dec 2020 16:47:26

US3602074

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 09:06:56
Query 'Data is required. Please complete.' answered with 'Data inserted in error' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 20:08:41
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 20:08:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:08:33
User entered 'No (N)'	(b) (4), (b) (6)	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered '30 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered '11:20' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User entered '30 Dec 2020 11:20'	System	30 Dec 2020 23:18:35
User entered empty.	System	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered missing code ND - Not Done; reason for change New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
DataPoint set to visible.	System	30 Dec 2020 23:16:45
DataPoint set to invisible.	System	16 Dec 2020 20:08:02
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33
DataPoint set to visible.	System	11 Dec 2020 16:47:26

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered missing code ND - Not Done; reason for change New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
DataPoint set to visible.	System	30 Dec 2020 23:16:45
DataPoint set to invisible.	System	16 Dec 2020 20:08:02
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33
DataPoint set to visible.	System	11 Dec 2020 16:47:26



US3602074

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:11:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 11:58:15
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 23:19:12
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Dec 2020 23:18:35
User entered '96.6' F reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered 'Other (Other)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered 'Temporal/Forehead scanner was used'	(b) (4), (b) (6)	30 Dec 2020 23:18:35
reason for change: New Information		
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered '92' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User entered 'bpm'	System	30 Dec 2020 23:18:35
User entered empty.	System	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered '14' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User entered 'breaths/min'	System	30 Dec 2020 23:18:35
User entered empty.	System	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered '125' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33



**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User entered 'mmHg'	System	30 Dec 2020 23:18:35
User entered empty.	System	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:34:47
User entered '84' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:18:35
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13
User entered 'mmHg'	System	30 Dec 2020 23:18:35
User entered empty.	System	11 Dec 2020 16:48:33

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:13

US3602074

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:11:56

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:35:08
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:19:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 09:07:01
Query 'Data is required. Please complete.' answered with 'Data inserted in error' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 20:08:58
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 20:08:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:08:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 16:48:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 16:47:12

**US3602074**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:35:11
User entered '30 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:19:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 16:48:46
User entered '2 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 16:47:12

US3602074

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:11:56

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:35:52
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:19:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Dec 2020 09:06:38
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 03 DEC 2020 is recorded under Convalescence Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 09:06:35
Query 'Data is required. Please complete.' answered with 'Data inserted in error' (Site from System).	(b) (4), (b) (6)	16 Dec 2020 20:09:47
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 03 DEC 2020 is recorded under Convalescence Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Data inserted in error' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 20:09:40
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Dec 2020 20:09:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:09:32



US3602074

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:11:56

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 03 DEC 2020 is recorded under Convalescence Visit Day 28 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:06:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 16:44:43

US3602074

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:11:56

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:35:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 04:35:52
User entered '30 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 23:19:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 20:09:32
User entered '3 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 16:49:11
User entered '2 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 16:46:37
User entered '3 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 16:44:43

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:34:43

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:34:43

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:34:43

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 00:34:43

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:23:24



**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:23:24

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:40:22
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 09:40:22
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered '1'	System	20 Jan 2021 00:58:06



**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'I'	System	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered empty.	System	20 Jan 2021 01:01:30
DataPoint set to visible.	System	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered empty.	System	20 Jan 2021 01:01:30
DataPoint set to visible.	System	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Jan 2021 01:01:30



**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '12:30'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered '18 Jan 2021 12:30'	System	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '97'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30



**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'bpm'	System	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'breaths/min'	System	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '145'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'mmHg'	System	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '88'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'mmHg'	System	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30



**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:11:56**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered empty.	System	20 Jan 2021 01:01:30
DataPoint set to visible.	System	20 Jan 2021 00:58:06

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '13:30'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered '18 Jan 2021 13:30'	System	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30



**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '92'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'bpm'	System	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'breaths/min'	System	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '109'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'mmHg'	System	20 Jan 2021 01:01:30



**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '82'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'mmHg'	System	20 Jan 2021 01:01:30

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:15

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:15

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:59:08

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:59:08

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:59:08

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'mRNA-1273'	System	20 Jan 2021 00:59:08
DataPoint set to visible.	System	20 Jan 2021 00:58:06



**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:59:08

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '13:00'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:59:08

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered '18 Jan 2021 13:00'	System	20 Jan 2021 00:59:08

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:59:08

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'ONCE'	System	20 Jan 2021 00:59:08

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 00:59:08

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:32

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:32



**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '12:30'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:32

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered '18 Jan 2021 12:30'	System	20 Jan 2021 00:58:32

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:48

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:48

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '12:28'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 00:58:48

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered '18 Jan 2021 12:28'	System	20 Jan 2021 00:58:48

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 01:01:41

**US3602074**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:39:17
User entered 'I'	System	20 Jan 2021 01:01:41



**US3602074**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:48:23

**US3602074**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:48:23

**US3602074**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:48:23

**US3602074**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:48:23

**US3602074**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:48:30

**US3602074**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'I'	System	25 Jan 2021 22:48:30

**US3602074**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered '1'	System	25 Jan 2021 22:48:30
DataPoint set to visible.	System	25 Jan 2021 22:48:30

**US3602074**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:22:48



**US3602074**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:22:48

**US3602074**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:22:48

**US3602074**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'OLD29'	System	16 Feb 2021 20:22:48

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '13:40'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered '15 Feb 2021 13:40'	System	16 Feb 2021 20:27:56



**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '98'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'bpm'	System	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'breaths/min'	System	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '117'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56



**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'mmHg'	System	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '84'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'mmHg'	System	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '15:00'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered '15 Feb 2021 15:00'	System	16 Feb 2021 20:27:56



**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '82'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'bpm'	System	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '16'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'breaths/min'	System	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '130'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56



**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'mmHg'	System	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '77'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'mmHg'	System	16 Feb 2021 20:27:56

**US3602074**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:23:11

**US3602074**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:23:11

**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:23:55

**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:23:55

**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:23:55



**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'mRNA-1273'	System	16 Feb 2021 20:23:55
DataPoint set to visible.	System	25 Jan 2021 22:48:30

**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:23:55

**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '14:25'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:23:55

**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered '15 Feb 2021 14:25'	System	16 Feb 2021 20:23:55

**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:23:55

**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'ONCE'	System	16 Feb 2021 20:23:55

**US3602074**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 20:23:55

**US3602074**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 20:38:00



**US3602074**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'I'	System	16 Feb 2021 20:38:00

**US3602074**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:01:10

**US3602074**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:01:10

**US3602074**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:01:10

**US3602074**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:11:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:01:10

**US3602074**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 15:01:23

**US3602074**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:11:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'I'	System	24 Feb 2021 15:01:23

**US3602074**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:27:30



**US3602074**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:27:30

**US3602074**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:27:30

**US3602074**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:11:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'OLD57'	System	17 Mar 2021 03:27:30

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '10:35'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered '12 Mar 2021 10:35'	System	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21



**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '75'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'bpm'	System	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'breaths/min'	System	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '118'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'mmHg'	System	17 Mar 2021 03:32:21



**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:06:39
User entered '83'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered 'mmHg'	System	17 Mar 2021 03:32:21

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09

**US3602074**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:11:56**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09

**US3602074**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:28:05

**US3602074**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:11:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:28:05

**US3602074**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:28:25

**US3602074**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:28:25



**US3602074**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
User entered '10:55'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 03:28:25

**US3602074**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:49:09
User entered '12 Mar 2021 10:55'	System	17 Mar 2021 03:28:25

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:11:56**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:30:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 16:08:11

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:57:04
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 14:57:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:56:49
User entered	System	14 Dec 2020 14:56:34
'USA-US079-2020-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	14 Dec 2020 14:56:34

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 22:41:53
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 22:41:13
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:19:01
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)	11 Dec 2020 18:46:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 18:46:48
Data point term sent to Coder	System	11 Dec 2020 18:45:34
User entered 'Symptomatic Covid - 19'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:19:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:19:05
User entered 'No (N)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:19:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30



US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:38:27
User entered '29 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 22:43:23
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 22:42:09
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:40:46
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 22:39:46
User entered '1 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 22:39:46
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:19:08
User closed query 'PV Query: COVID-19 symptoms have been reported starting on 29 Nov 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	20 Dec 2020 18:28:15
Query 'PV Query: COVID-19 symptoms have been reported starting on 29 Nov 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 19:07:02
User entered '29 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	18 Dec 2020 19:06:54
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 29 Nov 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:49:52
User entered '1 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 22:17:43
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).	(b) (4), (b) (6)	14 Dec 2020 04:41:26
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Time indicated in EMR, inserted as such' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 18:45:53
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 Dec 2020 18:45:30
User entered '19:00'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Nov 2020 19:00'	System	06 Jan 2021 22:43:23
User entered '1 Dec 2020 19:00'	System	06 Jan 2021 22:39:46
User entered '29 Nov 2020 19:00'	System	18 Dec 2020 19:06:54
User entered '1 Dec 2020 19:00'	System	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 22:17:27
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Dec 2020 22:36:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:44:38
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:08:53
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Per source, "Pt recovered From symptomatic COVID-19 infection with no residual sequale and returned to his baseline on 2/11/21". End date updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 20:00:15
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 19:59:23
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 19:59:23
User entered '11 Feb 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Apr 2021 19:59:23
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 19:13:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:17:25
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Dec 2020 22:36:21
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	30 Dec 2020 22:36:21
User entered '20 Dec 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Dec 2020 22:36:21
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Dec 2020 22:35:32

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	20 Dec 2020 18:28:41
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'This A.E is still on-going, will update end date when EMR is updated with providers notes. Thank you.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 21:41:31
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:48:44
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:17:22
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:01:36
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:00:45
User entered empty.	System	11 Dec 2020 18:45:30



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:17:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Was this SAE reported within 24 hours of awareness to Moderna's safety group? Please clarify.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 04:00:06
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Query 'Was this SAE reported within 24 hours of awareness to Moderna's safety group? Please clarify.' answered with 'Data was sent to Moderna Safety Board on Jan4th 2021', per source documentation on 1/8' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:47:50
User opened query 'Was this SAE reported within 24 hours of awareness to Moderna's safety group? Please clarify.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 23:12:18
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:17:20
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	18 Dec 2020 19:07:24
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Dec 2020 19:07:24
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	11 Dec 2020 18:45:30
User entered 'No (N)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 22:19:11
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 22:19:12
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:19:15
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Dec 2020 08:32:36
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Admission Date is inserted. Subject recently got admitted on 12/10; subject did not get discharge as of yet. Subject was not admitted in ICU per EMR' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 18:47:13
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	11 Dec 2020 18:45:30
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:34:43
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:12:23
User entered '20 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	28 Dec 2020 22:09:17
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 22:34:50
User entered 'No (N)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:35:52
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:12:31
User entered '1' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 22:35:32
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:12:38
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:12:40
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'PV Query: Study drug assessment reported as not applicable; previously reported as not related. Should be answered as related or not related.' (Site from Safety).	(b) (4), (b) (6)	20 Jan 2021 19:55:46
Query 'PV Query: Study drug assessment reported as not applicable; previously reported as not related. Should be answered as related or not related.' answered with 'Updated per source.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 17:24:04
DataPoint Un-verified.	(b) (4), (b) (6)	19 Jan 2021 17:23:43
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	19 Jan 2021 17:23:43
User opened query 'PV Query: Study drug assessment reported as not applicable; previously reported as not related. Should be answered as related or not related.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 22:00:18
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:12:43
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 22:35:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:12:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:12:47
User closed query 'PV Query: As the last dose of study drug was given on 19 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 14:56:30
Query 'PV Query: As the last dose of study drug was given on 19 Oct 2020, please update the action taken with study drug from none to not applicable.'	(b) (4), (b) (6)	05 Jan 2021 21:05:37
answered with 'Updated' (Site from Safety).		
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Jan 2021 21:05:31
reason for change: Per Query Resolution		
User opened query 'PV Query: As the last dose of study drug was given on 19 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 19:06:02
User entered 'None (NONE)' reason for change:	(b) (4), (b) (6)	30 Dec 2020 22:35:32
New Information		
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:12:54
User entered '0'	(b) (4), (b) (6)	11 Dec 2020 18:45:30



US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:12:57
User closed query ' Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:27:08
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Dec 2020 18:29:49
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'EMR states "Concomitant medication x based on pts conversation with me reg the inpatient meds that were provided to him". Provider unable to acquire medication details due to subject's inability to recall details" (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 19:13:23
Query ' Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please consider to complete the ConMed forms. Thank you. ' answered with 'EMR states "Concomitant medication x based on pts conversation with me reg the inpatient meds that were provided to him". Provider unable to acquire medication details due to subject's inability to recall details' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:12:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:49:29
User opened query ' Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:05:40
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

US3602074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: RQ: Response noted, however, OXYGEN SUPPLEMENTATION is already recorded as a Con Med and it is delivered via NASAL CANNULA. Please review and consider removing NASAL CANNULA in the Con Proc eCRF and update the response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 15:35:40
Query 'Per DM CLR: RQ: Response noted, however, OXYGEN SUPPLEMENTATION is already recorded as a Con Med and it is delivered via NASAL CANNULA. Please review and consider removing NASAL CANNULA in the Con Proc eCRF and update the response as appropriate. Otherwise, clarify.' answered with 'Done per query instructions. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 19:36:12
User opened query 'Per DM CLR: RQ: Response noted, however, OXYGEN SUPPLEMENTATION is already recorded as a Con Med and it is delivered via NASAL CANNULA. Please review and consider removing NASAL CANNULA in the Con Proc eCRF and update the response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 06:37:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Other Action Taken field' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:43:46
Query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Other Action Taken field' answered with 'Chest X-rays and Nasal Cannula added as Con Procedure' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 15:10:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, However, there is no procedure recorded that matches this AE within this timeframe. Diagnostic procedures are not considered treatment. Please review and add procedure as appropriate or update Other Action Taken field' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 02:31:42
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:13:04
User closed query 'Per CDM: Concomitant Procedure checkbox is selected however, corresponding procedure page is missing. Please confirm and consider to complete the Concomitant Procedure forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 11:01:45
Query 'Per CDM: Concomitant Procedure checkbox is selected however, corresponding procedure page is missing. Please confirm and consider to complete the Concomitant Procedure forms. Thank you. ' answered with 'Added a con procedure per EMR' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:15:40
User opened query 'Per CDM: Concomitant Procedure checkbox is selected however, corresponding procedure page is missing. Please confirm and consider to complete the Concomitant Procedure forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:07:16
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:13:07
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 15:13:51
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 22:36:43
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 22:35:32
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:49:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:14:05
User entered 'Recovering with sequelae with Resting tachycardia and exertional dyspnea and requiring nasal oxygen supplementation' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 22:35:32
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:45:30

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:24
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per CDM Re-Query: Please confirm what was updated as OXIGEN SUPPLEMENTATION is not recorded on ConProc or ConMed CRF. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 10:36:18
User closed query 'Per DM CLR: SAE Narrative = RESTING TACHYCARDIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 16:32:08
Query 'Per CDM Re-Query: Please confirm what was updated as OXIGEN SUPPLEMENTATION is not recorded on ConProc or ConMed CRF. Thank you' answered with 'Oxygen Supplementation confirmed by provider. Media Section of source under flowsheets--> ETC Vitals--> started Oxygen on 12/10/2020. Will document in Con Meds. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 19:44:34
Query 'Per DM CLR: SAE Narrative = RESTING TACHYCARDIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'Per provider, "Pt with Severe COVID and the resting tachycardia And persistent requirement of the oxygen was associated with the same COVID syndrome and is not a separate AE". Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 19:27:59
User opened query 'Per CDM Re-Query: Please confirm what was updated as OXIGEN SUPPLEMENTATION is not recorded on ConProc or ConMed CRF. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:06:59
User closed query 'Per DM CLR: Narrative = OXYGEN SUPPLEMENTATION. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:06:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = CT SCAN . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 16:02:47
Query 'Per DM CLR: Narrative = OXYGEN SUPPLEMENTATION. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 18:24:45
Query 'Per DM CLR: Narrative = CT SCAN . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated. CT Scan documented in error.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 18:15:51



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WITH SEVERE HYPOXEMIA AT HOME AND COUGH AND CHEST PAIN AND THUS WENT TO THE ED AND IS CURRENTLY ADMITTED WITH NEED FOR OXYGEN SUPPLEMENTATION AND MEDICATIONS FOR THE SAME . PT STARTED ON ANTIBIOTICS , REMDESEVIR AND STEROIDS .  PT SINCE THE LAST VISIT HAD VISITED THE ER ON 12/8 AND DCED HOME WITHOUT ANY INVESTIGATIONS BEING DONE DUE TO PULSE OF OF &gt; 95% ON ROOM AIR  HE WENT BACK TO THE HOSPITAL ON 12/10 DUE TO SIG HYPOXEMIA AND CHEST WALL PAIN AND PLEURISY ASSOCIATED WITH COUGH AND WAS THEN ADMITTED FOR 10D AND DCED ON 12/20/20 . THE HAD RESP FAILURE WITH NADIR OXYGEN ON ROOM AIR OF 85 % . PT RECEIVED STEROIDS , REMDESIVIR AND OXYGEN SUPPLEMENTATION. HE WAS DCED ON 2 LIT NASAL CANULA SINCE WAS SON ON WALKING ( EXERTIONAL DYSPNEA) AND WITH RESTING TACHYCARDIA ( BASELINE PRIOR TO ILLNESS ~ 80S AND NOW IN THE MID 90S).  COUGH IS IMPROVING BUT STILL ONGOING AND TAKING PHENARGAN SYRUP PRN FOR THE SAME . HE WAS PLACED ON ANTICOAGULATION IN HOSPITAL AND WAS DCED ON BABY ASA 81 MG PO DAILY .  HE IS TAKING VIT D 2000U , VIT C 1000MG AND ZINCE 100MG PO DAILY  NO OTHER VITAMINS OR SUPPLEMENTS TAKEN   3 KIDS ( 2 MILDLY SYMPTOMATIC AND ONE ASYMPTOMATIC ) AT HOME ALSO WERE POSITIVE FOR COVID THE SAME TIME AND HAVE SINCE RECOVERED . WIFE TESTED MULTIPLE TIMES WAS NEGATIVE    ROS : NO BILATERAL KNEE PAIN OR MYALGIAS ( BOTH ENDED 3D INTO HOSPITAL STAY : 12/13/20 )' reason for change: New Information	(b) (4), (b) (6)	10 Feb 2021 18:15:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = RESTING TACHYCARDIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:25:29
User opened query 'Per DM CLR: Narrative = OXYGEN SUPPLEMENTATION. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:25:16
User opened query 'Per DM CLR: Narrative = CT SCAN . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 23:25:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 19:30:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Any and all relevant laboratory and diagnostic test results including units and reference ranges were uploaded in source under the "Media" tab.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 01:49:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WITH SEVERE HYPOXEMIA AT HOME AND COUGH AND CHEST PAIN AND THUS WENT TO THE ED AND IS CURRENTLY ADMITTED WITH NEED FOR OXYGEN SUPPLEMENTATION AND MEDICATIONS FOR THE SAME . PT STARTED ON ANTIBIOTICS , REMDESEVIR AND STEROIDS .  Pt since the last visit had visited the ER on 12/8 and dced home without any investigations being done due to pulse of of &gt; 95% on room air  He went back to the hospital on 12/10 due to sig hypoxemia and chest wall pain and pleurisy associated with cough and was then admitted for 10d and dced on 12/20/20 . The had resp failure with nadir oxygen on room air of 85 % and CT scan with bilateral infiltrates . Pt received steroids , remdesivir and oxygen supplementation. He was dced on 2 Lit Nasal canula since was SON on walking ( exertional dyspnea) and with resting tachycardia ( baseline prior to illness ~ 80s and now in the mid 90s).  Cough is improving But still ongoing and taking Phenargan syrup prn for the same . He was placed on anticoagulation in hospital and was dced on Baby ASA 81 mg po daily .  He is taking VIt D 2000U , VIt C 1000mg and ZInce 100mg po daily  No other vitamins or supplements taken   3 kids ( 2 mildly symptomatic and one asymptomatic ) at home also were positive for COVID the same time and have since recovered . Wife tested multiple times was negative    ROS : no bilateral knee pain or myalgias ( both ended 3d into hospital stay : 12/13/20 )' reason for change: New Information	(b) (4), (b) (6)	06 Jan 2021 22:45:29
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 19:05:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Safety Medical Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:13:01
Query 'Safety Medical Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'Done. Email was sent to Moderna per (b) (6) Research Nurse Coordinator on 12/30. An additional clarification was also sent this morning per (b) (6). ' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 21:59:16
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 15:13:48
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 15:13:46
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 15:18:30
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Updated' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 23:07:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:11:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: COVID-19 symptoms have been reported starting on 29 Nov 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:52:49
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:52:35
Query 'PV Query: COVID-19 symptoms have been reported starting on 29 Nov 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' answered with 'Start Date updated to 11/29' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 22:10:32
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Hospital discharge date provided and inserted per EMR' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 22:09:52
User opened query 'PV Query: COVID-19 symptoms have been reported starting on 29 Nov 2020. Please update the event start date to reflect the date that the subject first experienced symptoms, as per the protocol. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:02:03
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 14:01:31
User opened query 'Safety Medical Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:59:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:49:00

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EAB) (1725)

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 15:48:28
User entered 'Pt with severe hypoxemia at home and cough and chest pain and thus went to the ED and is currently admitted with need for oxygen supplementation and medications for the same . Pt started on Antibiotics , remdesevir and steroids .'	(b) (4), (b) (6)	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Dec 2020 19:07:24
User entered '0'	System	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Dec 2020 18:45:30



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Dec 2020 18:45:30

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:09:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:06:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:06:50
Data point term sent to Coder	System	18 Dec 2020 20:05:25
User entered 'Bilateral knee pain'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:00
User entered 'No (N)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:05
User entered 'No (N)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:29
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:40:55
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4)	
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'Updated.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 00:36:20
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 22:31:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 22:30:36
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 21:31:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'PV Query: Since an event of Covid-19 has been reported, and this event is not the diagnosis itself, please update answer to 'No.' ' (Site from Safety).	(b) (4)	
Query 'PV Query: Since an event of Covid-19 has been reported, and this event is not the diagnosis itself, please update answer to 'No.' ' answered with 'This A.E is associated with covid-19' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 19:29:43
User opened query 'PV Query: Since an event of Covid-19 has been reported, and this event is not the diagnosis itself, please update answer to 'No.' ' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 01:29:20
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 18:00:05
	(b) (4), (b) (6)	07 Jan 2021 19:08:46

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EAB) (1725)

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**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	07 Jan 2021 19:08:46
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:10:07
User entered 'No (N)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:09
User entered '29 Nov 2020'	(b) (4), (b) (6)	18 Dec 2020 20:05:20



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:11
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User entered empty.	System	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:13
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 22:31:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

US3602074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:11:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:17
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Dec 2020 22:31:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	30 Dec 2020 22:31:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Dec 2020 22:31:16
User entered '13 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	30 Dec 2020 22:31:16
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:19
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User entered empty.	System	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:23
User entered 'No (N)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:26
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:30
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:31
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:33
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:36
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:37
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:40
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:41
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:05:20



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:43
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:45
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:48
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:10:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'l'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:05:20



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	30 Dec 2020 22:31:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User entered '0'	System	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47
User entered '0'	System	18 Dec 2020 20:05:20

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:57:47

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:34
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 18:01:30

US3602074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:34
User closed query 'Is lightheadedness a symptom of a condition? If yes, please record the condition and associated details.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 04:00:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Query 'Is lightheadedness a symptom of a condition? If yes, please record the condition and associated details.' answered with 'Lightheadedness is a symptom of covid-19 per EMR. YES was selected to the question "Is this event a confirmed diagnosis of Symptomatic Covid-19?".' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 19:07:44
User opened query 'Is lightheadedness a symptom of a condition? If yes, please record the condition and associated details.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 20:39:28
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Lightheadedness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:09:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 20:09:52
Data point term sent to Coder	System	18 Dec 2020 20:08:28
User entered 'Lightheadedness'	(b) (4), (b) (6)	18 Dec 2020 20:08:13



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:52:00
User entered 'No (N)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:52:03
User entered 'No (N)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

US3602074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:11:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:11:34
User signature succeeded.	Bindu Balani (b) (4)	13 Mar 2021 23:40:55
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4)	
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'Updated.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 00:36:59
Signature has been broken.	(b) (4), (b) (6)	10 Mar 2021 22:31:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 22:31:23
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 21:32:13
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'PV Query: Since an event of Covid-19 has been reported, and this event is not the diagnosis itself, please update answer to 'No.' ' (Site from Safety).	(b) (4)	
Query 'PV Query: Since an event of Covid-19 has been reported, and this event is not the diagnosis itself, please update answer to 'No.' ' answered with 'Yes was selected because this A.E is associated with covid-19	(b) (4), (b) (6)	12 Jan 2021 19:29:25
' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 01:29:56
User opened query 'PV Query: Since an event of Covid-19 has been reported, and this event is not the diagnosis itself, please update answer to 'No.' ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 18:01:26

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:01
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	07 Jan 2021 19:07:01
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:55:47
User entered 'No (N)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:55:54
User entered '5 Dec 2020'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:55:56
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User entered empty.	System	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:56:04
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 20:08:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 20:08:24
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 20:08:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:56:07
User entered '5 Dec 2020'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	06 Jan 2021 20:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 20:56:39
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:56:23
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User entered empty.	System	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:56:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:56:46
User entered 'No (N)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:56:53
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:56:54
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:56:56
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:08:13



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:56:57
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:56:59
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:00
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:01
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:08
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:11
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:13
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:15
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:25
User entered 'l'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:26
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:29
User entered '0'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:34
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:57:36
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 20:08:13



**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User entered '0'	System	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12
User entered '0'	System	18 Dec 2020 20:08:13

**US3602074**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:58:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:11:56**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:11:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 19:46:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per progress note dated 12/30/20, subject received steroids, remdesivir, 2 Lit Canula SON on walking, and oxygen supplementation. Please add to ConMed section.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	01 Mar 2021 04:02:25
Query 'Per progress note dated 12/30/20, subject received steroids, remdesivir, 2 Lit Canula SON on walking, and oxygen supplementation. Please add to ConMed section.' answered with 'Per PI all Con Meds were uploaded in the Media tab of source.' (Site from CRA). DataPoint Verified.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Query 'Per progress note dated 12/30/20, subject received steroids, remdesivir, 2 Lit Canula SON on walking, and oxygen supplementation. Please add to ConMed section.' answered with 'Per PI all Con Meds were uploaded in the Media tab of source.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 15:53:47
User opened query 'Per progress note dated 12/30/20, subject received steroids, remdesivir, 2 Lit Canula SON on walking, and oxygen supplementation. Please add to ConMed section.' (Site from CRA). User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: ZEAXANTHIN, PRODUCTSYNONYM: LUTEIN [ZEAXANTHIN] - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	06 Jan 2021 23:07:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	06 Jan 2021 23:07:25
Data point term sent to Coder Coding entries removed.	Coder Import (b) (4)	24 Nov 2020 12:14:45
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: XANTOFYL;ZEAXANTHIN, PRODUCTSYNONYM: LUTEINE [XANTOFYL;ZEAXANTHIN] - version WHODrug-Global-B3\\202003.	(b) (4)	24 Nov 2020 12:14:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	System	30 Oct 2020 18:21:58
	(b) (4), (b) (6)	30 Oct 2020 18:21:11
	Coder Import (b) (4)	29 Sep 2020 15:16:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 15:16:34
	(b) (4)	

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EAB) (1725)

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**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	21 Sep 2020 19:49:02
User entered 'Leutin Eye Drops'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:30
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:32
User entered 'for eye strength preventative'	(b) (4), (b) (6)	21 Sep 2020 19:48:58



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:34
User entered 'UNK'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:35
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:38
User entered 'Unknown'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:39
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:48:58

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:11:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 23:07:42
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:47:58
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'ophthalmic' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:21:15
User entered 'Other (OTHER)' reason for change:	(b) (4), (b) (6)	30 Oct 2020 18:21:11
Data Entry Error		
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:44:37
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:45
User entered 'ophthalmic' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:21:11
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:44
User entered 'UN UNK 2015'	(b) (4), (b) (6)	21 Sep 2020 19:48:58



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:47
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:49
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 23:07:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:48:58

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:48:58

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:21
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)	21 Sep 2020 19:51:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 19:51:49
Data point term sent to Coder	System	21 Sep 2020 19:51:05
User entered 'Multivitamin'	(b) (4), (b) (6)	21 Sep 2020 19:50:14



US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:11:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:55
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 19:50:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Sep 2020 19:50:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:50:21
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Sep 2020 19:50:14
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:23
User entered 'Preventive Health'	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:24
User entered 'UNK'	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:29
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:31
User entered 'Unknown'	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:35
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Sep 2020 19:50:14



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:38
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:41
User entered 'UN UNK 2015'	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:42
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:45
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:12:47
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:50:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:50:14



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 19:50:14

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:06
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:27:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:27:35
Data point term sent to Coder	System	06 Nov 2020 04:00:35
User entered 'Aleve (Naproxen) (dosage: unknown)'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:07
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:09
User entered 'Slight Headache'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:13
User entered '2'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:12
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:18
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:20
User entered 'once (ONCE)'	(b) (4), (b) (6)	06 Nov 2020 04:00:21



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:22
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:24
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:27
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:29
User entered '24 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:30
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:32
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:33
User entered '24 Oct 2020'	(b) (4), (b) (6)	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:13:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 04:00:21



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User entered empty.	System	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User entered empty.	System	06 Nov 2020 04:00:21

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:49:52
User entered empty.	System	06 Nov 2020 04:00:21

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:56:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 23:45:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 23:45:06
Data point term sent to Coder	System	04 Dec 2020 23:44:28
User entered 'Tylenol'	(b) (4), (b) (6)	04 Dec 2020 23:44:19

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:11:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:56:44
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:44:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 23:44:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 23:44:25
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:44:19
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:58:23
User entered 'Fever - listed on symptom tracker log'	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:58:27
User entered '500' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 23:46:47
User entered '1000'	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:58:29
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Dec 2020 23:44:19



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:09
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:11
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:12
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:15
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:17
User entered '2 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:19
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:20
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 23:44:19



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:22
User entered '2 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:00:27
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User entered empty.	System	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User entered empty.	System	04 Dec 2020 23:44:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:55
User entered empty.	System	04 Dec 2020 23:44:19

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 15:16:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 15:16:56
Data point term sent to Coder	System	04 Dec 2020 23:46:30
User entered 'Aleve (Naproxen)'	(b) (4), (b) (6)	04 Dec 2020 23:46:20

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:11:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:46:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 23:46:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 23:46:25
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:46:20
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered 'Fever - listed on symptom tracker log'	(b) (4), (b) (6)	04 Dec 2020 23:46:20



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered '440'	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered '2 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 23:46:20



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered '2 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:44:18
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User entered empty.	System	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User entered empty.	System	04 Dec 2020 23:46:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:50:58
User entered empty.	System	04 Dec 2020 23:46:20

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:35:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:35:48
Data point term sent to Coder	System	04 Dec 2020 23:49:31
User entered 'Zithromax Azithromycin'	(b) (4), (b) (6)	04 Dec 2020 23:49:14



US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:10
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:49:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 23:49:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 23:49:18
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:49:14
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:12
User entered 'Sore throat - listed on symptom tracker log'	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:14
User entered '500'	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:16
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:18
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:24
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:25
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Dec 2020 23:49:14



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:31
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:33
User entered '30 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:35
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:37
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 23:49:14

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:11:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
Query 'Subject was prescribed medication on 11/30/20 for 5 days. End date could not be 11/20/20. Verify end date and update data accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:20:32
User opened query 'Subject was prescribed medication on 11/30/20 for 5 days. End date could not be 11/20/20. Verify end date and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:20:21
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 19:18:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:48:38
User entered '30 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:41
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User entered empty.	System	04 Dec 2020 23:49:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User entered empty.	System	04 Dec 2020 23:49:14



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:10
User entered empty.	System	04 Dec 2020 23:49:14

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:35:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:35:48
Data point term sent to Coder	System	04 Dec 2020 23:50:32
User entered 'Zithromax Azithromycin'	(b) (4), (b) (6)	04 Dec 2020 23:50:12

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:57
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:50:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 23:50:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 23:50:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:50:12
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:48:58
User entered 'Sore throat - listed on symptom tracker log'	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:01
User entered '250'	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:02
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:04
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:08
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Dec 2020 23:50:12



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:10
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:15
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

**Start date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:55:17
User closed query 'Subject's first dose was 500 mg started on 11/30/20 once. All other doses following the first dose was 250 mg. Should this start date be 12/1/20? Please verify data and update, if necessary.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:55:15
Query 'Subject's first dose was 500 mg started on 11/30/20 once. All other doses following the first dose was 250 mg. Should this start date be 12/1/20? Please verify data and update, if necessary.' answered with 'Updated dates.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:01:22
User entered '1 Dec 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Jan 2021 22:00:58
User opened query 'Subject's first dose was 500 mg started on 11/30/20 once. All other doses following the first dose was 250 mg. Should this start date be 12/1/20? Please verify data and update, if necessary.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 18:51:16
User entered '30 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:37
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:55:21
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 22:02:38
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Jan 2021 22:02:38
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 23:50:12

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:11:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Subject was prescribed medication for 5 days. Please add stop date.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:55:25
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:55:22
Query 'Subject was prescribed medication for 5 days. Please add stop date.' answered with 'Stop date added. Thank you.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:03:03
User entered '5 Dec 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Jan 2021 22:02:38
User opened query 'Subject was prescribed medication for 5 days. Please add stop date.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 18:54:50
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 18:52:07
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 18:49:41
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:49:42
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 23:50:12



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User entered '1'	System	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User entered '1'	System	04 Dec 2020 23:50:12

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:14
User entered '804 (804)'	System	04 Dec 2020 23:50:12

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:21:36
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 15:21:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 15:21:58
Data point term sent to Coder	System	04 Dec 2020 23:58:33
User entered 'Aleve'	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:21:39
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:21:41
User entered 'Headache - listed in symptom tracker log'	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:21:44
User entered '220'	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:21:42
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Dec 2020 23:58:19



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:21:49
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:58:19

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	06 Jan 2021 22:05:39
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	06 Jan 2021 22:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 22:05:39
User entered 'once daily (QD)' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Jan 2021 22:05:39
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	06 Jan 2021 22:05:12
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:21:51
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:58:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 23:58:34
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 23:58:34
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 23:58:19
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:21:53
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:21:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:21:59
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:22:01
User entered '3 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:22:03
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 23:58:19

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:11:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:54:34
User closed query 'Query posted 1/6/21, is there a stop date? Please update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:54:32
Query 'Query posted 1/6/21, is there a stop date? Please update data accordingly.' answered with 'Updated per EMR.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:05:47
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Jan 2021 22:05:12
User opened query 'Query posted 1/6/21, is there a stop date? Please update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:23:56
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 19:22:44
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:22:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 23:58:19



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '6 Dec 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Jan 2021 22:05:39
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 22:05:12
User entered '9 Dec 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	06 Jan 2021 22:05:12
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:22:08
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:22:10
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User entered '1'	System	06 Jan 2021 22:05:39
User entered empty.	System	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User entered '1'	System	06 Jan 2021 22:05:39
User entered empty.	System	04 Dec 2020 23:58:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:18
User entered '804 (804)'	System	06 Jan 2021 22:05:39
User entered empty.	System	04 Dec 2020 23:58:19

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:26:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 09:02:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 09:02:44
Data point term sent to Coder	System	08 Dec 2020 22:14:14
User entered 'Vitamin C'	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:26:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:26:58
User entered 'Dietary/nutritional supplement'	(b) (4), (b) (6)	08 Dec 2020 22:14:09



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:01
User entered '1000'	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:02
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:04
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:06
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:07
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:10
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:28:29
Query 'Chart in progress notes, start date is 12/4/20. Please verify data and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:28:27
User opened query 'Chart in progress notes, start date is 12/4/20. Please verify data and update accordingly. (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:26:43
User entered '3 Dec 2020'	(b) (4), (b) (6)	08 Dec 2020 22:14:09



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:27:13
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:18
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:27:19
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 22:14:09

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 22:14:09

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 08:58:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 08:58:27
Data point term sent to Coder	System	08 Dec 2020 22:18:17
User entered 'Vitamin D'	(b) (4), (b) (6)	08 Dec 2020 22:18:16



US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:34:45
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:19:40
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 18:19:34
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	27 Jan 2021 18:19:34
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:14:14
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:28:36
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:37
User entered 'Dietary/nutritional supplement'	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:42
User entered '2000'	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:40
User entered 'IU (IU)'	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:44
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:48
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Dec 2020 22:18:16



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:54
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:18:16

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:11:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:28:55
Query 'Chart in progress notes, start date is 12/4/20. Please verify data and update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:28:18
User opened query 'Chart in progress notes, start date is 12/4/20. Please verify data and update accordingly. (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:27:45
User entered '3 Dec 2020'	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:28:59
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:28:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:01
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 22:18:16

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 22:18:16



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 22:18:16

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 08:11:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 08:11:09
Data point term sent to Coder	System	08 Dec 2020 22:20:20
User entered 'Zinc'	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:33
User entered 'DIETARY/NUTRITIONAL SUPPLEMENT'	(b) (4), (b) (6)	08 Dec 2020 22:20:14

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:11:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:34:59
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:22:53
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 18:22:37
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 18:22:37
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 15:15:30
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:29:35
User entered '1000'	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:36
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:38
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:41
User entered 'once daily (QD)'	(b) (4), (b) (6)	08 Dec 2020 22:20:14



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:45
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:52
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:54
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:29:55
User entered '3 Dec 2020'	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 19:29:57
User entered '0'	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:30:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:30:02
User entered empty.	(b) (4), (b) (6)	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 19:30:03
User entered 'No (N)'	(b) (4), (b) (6)	08 Dec 2020 22:20:14



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 22:20:14

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 22:20:14

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
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 HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 23:27:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 23:27:52
Data point term sent to Coder	System	10 Dec 2020 19:04:25
User entered 'Albuterol HFA (PROVENTIL, VENTOLIN, PROAIR) 108 (90 Base) MCG/ACT inhaler'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'No (N)'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Spasm of Lung Air Passages and Wheezing'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '2'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'puff (PUFF)'	(b) (4), (b) (6)	10 Dec 2020 19:03:57



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'other (OTHER)'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Every 6 hours as needed for Wheezing for up to 14 days'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '8 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 19:03:57



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'No (N)'	(b) (4), (b) (6)	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 19:03:57

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 19:03:57

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 23:41:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 23:41:10
Data point term sent to Coder	System	10 Dec 2020 19:05:29
User entered 'Benzonatate (TESSALON)'	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'No (N)'	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Cough'	(b) (4), (b) (6)	10 Dec 2020 19:05:26



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '100'	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'three times daily (TID)'	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '8 Dec 2020'	(b) (4), (b) (6)	10 Dec 2020 19:05:26



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '0'	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'No (N)'	(b) (4), (b) (6)	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Dec 2020 19:05:26

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Dec 2020 19:05:26

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:13:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 04:13:02
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	07 Jan 2021 17:14:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:31:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:31:23
Data point term sent to Coder	System	30 Dec 2020 23:11:02
User entered 'Asprin'	(b) (4), (b) (6) (b) (4)	30 Dec 2020 23:10:19



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'prevention of clots'	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '81'	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Dec 2020 23:10:19



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '21 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '0'	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 23:10:19

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:11:56

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:57:17
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 17:26:44
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:26:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 17:26:38
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 05:46:55
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:14:15

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 23:10:19



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 23:10:19

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Dec 2020 23:10:19

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PHENOTHIAZINE DERIVATIVES, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:29:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:29:31
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:11:20
Data point term sent to Coder	System	11 Feb 2021 22:11:08
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:11:03
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PHENOTHIAZINE DERIVATIVES, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:40:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:40:22
Data point term sent to Coder	System	30 Dec 2020 23:12:02
User entered 'Phenergan'	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Dec 2020 23:11:37

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR RQ: Per previous query response "Updated"; however, the update is not obvious, please update the "Indication" field as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 02:36:42
Query 'Per DM CLR RQ: Per previous query response "Updated"; however, the update is not obvious, please update the "Indication" field as appropriate.' answered with 'Phenergan is being used to treat "cough" that was documented during this subject's illness visit. Cough was tracked in symptom tracker/symptom log located in covid-19 assessment dated 29th of Nov 2020. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 22:51:58
User opened query 'Per DM CLR RQ: Per previous query response "Updated"; however, the update is not obvious, please update the "Indication" field as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:05:16
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:56:33
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Updated. Cough Suppressant is the indication because Phenergan was used during subject's illness visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:11:35
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 22:11:03
User entered 'COUGH SUPPRESSANT' - captured in illness visit' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:11:03

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 05:51:52
	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Cough suppressant'	(b) (4), (b) (6)	30 Dec 2020 23:11:37

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 25 mg, etc) instead of mL count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:21:12
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 25 mg, etc) instead of mL count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Source states "5ml", inserted as such.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:10:44
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 25 mg, etc) instead of mL count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 05:52:11
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '5'	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'mL (mL)'	(b) (4), (b) (6)	30 Dec 2020 23:11:37



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'three times daily (TID)'	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '21 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered '0'	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 23:11:37



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 23:11:37

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:11:56

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 16:56:43
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.'	(b) (4), (b) (6)	11 Feb 2021 17:27:40
answered with 'Updated.' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 17:27:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 17:27:32
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 05:52:23
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:14:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 23:11:37

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Dec 2020 23:11:37

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 17:59:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 17:59:42
Data point term sent to Coder	System	08 Jan 2021 17:59:19
User entered 'Melatonin'	(b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:37:24
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	11 Feb 2021 22:16:11
' answered with 'Medication was taken by subject while being admitted. Please see Media section in source for more details. Thank you.' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	11 Feb 2021 05:56:53
' (Site from DM).		
User entered 'Insomnia'	(b) (4), (b) (6)	08 Jan 2021 17:59:17



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '9'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'NIGHTLY'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '19 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User entered empty.	System	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User entered empty.	System	08 Jan 2021 17:59:17

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:53
User entered empty.	System	08 Jan 2021 17:59:17

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:56
Data point term sent to Coder	System	11 Feb 2021 22:17:14
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:16:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:44
Data point term sent to Coder	System	08 Jan 2021 18:06:25
User entered 'Dexamethasone PF (DECADRON PF)'	(b) (4), (b) (6)	08 Jan 2021 18:05:40



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'COVID'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '6'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 24 HOURS'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	11 Feb 2021 22:16:50
reason for change: Per Query Resolution	(b) (4), (b) (6)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 18:05:40



US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:11:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:24:36
Query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:16:56
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:16:50
User opened query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 05:59:07
User entered 'injection'	(b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	(b) (4), (b) (6)	19 Feb 2021 22:11:20
User entered '18 Dec 2020'	(b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User entered empty.	System	08 Jan 2021 18:05:40

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User entered empty.	System	08 Jan 2021 18:05:40



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:51:58
User entered empty.	System	08 Jan 2021 18:05:40

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:19:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:19:45
Data point term sent to Coder	System	08 Jan 2021 18:09:26
User entered 'Polyethylene glycol (MIRALAX) packet 17 g'	(b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:44:00
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' answered with 'This medication was taken during subject's hospitalization. Please see "Media" section in source for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:17:42
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:03:15
User entered 'Constipation'	(b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '17'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:08:52



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered '1'	System	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered '1'	System	08 Jan 2021 18:08:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:04
User entered '804 (804)'	System	08 Jan 2021 18:08:52

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:46
Data point term sent to Coder	System	08 Jan 2021 18:19:32
User entered 'Docusate (COLACE) liquid'	(b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:44:25
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' answered with 'This medication was taken during subject's hospitalization. Please see "Media" section in source for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:17:55
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:03:53
User entered 'Constipation'	(b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '100'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '2 TIMES DAILY PRN'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User entered empty.	System	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User entered empty.	System	08 Jan 2021 18:18:55

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:09
User entered empty.	System	08 Jan 2021 18:18:55

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:42:54
Data point term sent to Coder	System	11 Feb 2021 22:19:16
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:18:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:12:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:12:45
Data point term sent to Coder	System	08 Jan 2021 18:24:33
User entered 'Enoxaparin (LOVENOX)'	(b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Prevention of Blood clots'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '40'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 12 HOURS SCHEDULED'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	11 Feb 2021 22:18:17
reason for change: Per Query Resolution	(b) (4), (b) (6)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 18:24:10

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:11:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:26:26
Query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:18:23
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:18:17
User opened query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:04:22
User entered 'injection'	(b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User entered empty.	System	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User entered empty.	System	08 Jan 2021 18:24:10

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:14
User entered empty.	System	08 Jan 2021 18:24:10

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 16:34:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 16:34:56
Data point term sent to Coder	System	12 Jan 2021 01:20:11
Coding entries removed.	(b) (4), (b) (6)	12 Jan 2021 01:19:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:37:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:37:45
Data point term sent to Coder	System	08 Jan 2021 18:36:41
User entered 'Vancomycin 1.5 g in NS 500 mL IVPB (PREMIX)'	(b) (4), (b) (6)	08 Jan 2021 18:35:51



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:44:51
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' answered with 'This medication was taken during subject's hospitalization - Bacteremia was just one of the many symptoms the subject experienced. Please see "Media" section in source for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:24:45
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:08:45
User entered 'Bacteremia'	(b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '1.5/500'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'g/mL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 12 HOURS INTERVAL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:11:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	(b) (4)	12 Jan 2021 01:20:08
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	12 Jan 2021 01:19:53
User entered 'Intravenous (INTRAVENOUS)' reason for change: New Information	(b) (4), (b) (6)	12 Jan 2021 01:19:53
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 18:35:51



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty; reason for change New Information	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:20:08
User entered 'IVPB'	(b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User entered empty.	System	08 Jan 2021 18:35:51

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User entered empty.	System	08 Jan 2021 18:35:51



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:18
User entered empty.	System	08 Jan 2021 18:35:51

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: IMODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:12:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	09 Jan 2021 00:12:45
Data point term sent to Coder	System	08 Jan 2021 18:37:42
User entered 'loperamide (IMODIUM)'	(b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no Diarrhea recorded in Symptom Tracker and AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:38:11
Query 'Per DM CLR: Please note there is no Diarrhea recorded in Symptom Tracker and AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' answered with 'This medication was taken during subject's hospitalization "Diarrhea" was on of the many symptoms the subject had to experience. Please see "Media" section in source for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:25:22
User opened query 'Per DM CLR: Please note there is no Diarrhea recorded in Symptom Tracker and AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:24:12
User entered 'Diarrhea'	(b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '2'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 6 HOURS PRN'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:37:03



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User entered empty.	System	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User entered empty.	System	08 Jan 2021 18:37:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:25
User entered empty.	System	08 Jan 2021 18:37:03

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN HYDROCHLORIDE, PRODUCTSYNONYM: VANCOCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 16:34:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Jan 2021 16:34:55
Data point term sent to Coder	System	12 Jan 2021 01:23:12
Coding entries removed.	(b) (4), (b) (6)	12 Jan 2021 01:22:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN HYDROCHLORIDE, PRODUCTSYNONYM: VANCOCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:36:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:36:45
Data point term sent to Coder	System	08 Jan 2021 18:48:50
User entered 'Vancomycin (VANCOCIN) 1 g in 200 mL NS (FROZEN PREMIX)'	(b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:25:59
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' answered with 'This medication was taken during subject's hospitalization. Please see "Media" section in source for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:25:35
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:27:19
User entered 'Bacteremia'	(b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '1/200'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'g/mL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 12 HOURS INTERVAL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: New Information	(b) (4), (b) (6)	12 Jan 2021 01:22:25
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty; reason for change New Information	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:22:25
User entered 'PREMIX via IV'	(b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User entered empty.	System	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User entered empty.	System	08 Jan 2021 18:48:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:29
User entered empty.	System	08 Jan 2021 18:48:34

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 18:53:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:53:42
Data point term sent to Coder	System	08 Jan 2021 18:52:50
User entered 'Melatonin'	(b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:39:36
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' answered with 'This medication was taken during subject's hospitalization. Please see "Media" section in source for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:25:50
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:27:58
User entered 'Insomnia'	(b) (4), (b) (6)	08 Jan 2021 18:52:03



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '3'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'NIGHTLY'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '12 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '19 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User entered empty.	System	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User entered empty.	System	08 Jan 2021 18:52:03

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:37
User entered empty.	System	08 Jan 2021 18:52:03

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: ULTRAM [TRAMADOL HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:33:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:33:45
Data point term sent to Coder	System	08 Jan 2021 18:53:51
User entered 'Tramadol (ULTRAM)'	(b) (4), (b) (6)	08 Jan 2021 18:53:32



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR RQ: Site response noted. However, please update the "Indication" to include the type and/or location of Pain (arms, Legs, Generalized, etc.), else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 02:36:07
Query 'Per DM CLR RQ: Site response noted. However, please update the "Indication" to include the type and/or location of Pain (arms, Legs, Generalized, etc.), else clarify.' answered with 'The type and/or location of pain is unknown per source, these progress notes and entries were made by hospital staff. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 22:53:17
User opened query 'Per DM CLR RQ: Site response noted. However, please update the "Indication" to include the type and/or location of Pain (arms, Legs, Generalized, etc.), else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:01:12
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:01:12
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:40:45
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'This medication was taken during subject's hospitalization. Please see "Media" section in source for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:26:33

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' answered with 'Pain relief was all that was specified in source doc from hospitalization.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:26:25
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:29:36
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:28:55
User entered 'Pain relief'	(b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '50'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 8 HOURS PRN'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User entered empty.	System	08 Jan 2021 18:53:32



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User entered empty.	System	08 Jan 2021 18:53:32

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:40
User entered empty.	System	08 Jan 2021 18:53:32

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:57
Data point term sent to Coder	System	11 Feb 2021 22:27:28
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:26:53
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:45
Data point term sent to Coder	System	08 Jan 2021 19:09:00
User entered 'Dexamethasone PF (DECADRON PF)'	(b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'COVID'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '6'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 12 HOURS SCHEDULED'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	11 Feb 2021 22:26:53
reason for change: Per Query Resolution	(b) (4), (b) (6)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 19:08:22

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:11:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:40:17
Query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:27:00
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:26:53
User opened query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:31:10
User entered 'injection'	(b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User entered empty.	System	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User entered empty.	System	08 Jan 2021 19:08:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:44
User entered empty.	System	08 Jan 2021 19:08:22

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:50:40
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 Mar 2021 07:50:40
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:11:20
Data point term sent to Coder	System	11 Feb 2021 22:28:31
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:27:41
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:28:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:28:45
Data point term sent to Coder	System	08 Jan 2021 19:12:03
User entered 'Remdesivir (VEKLURY) 200 mg in NS 250 mL'	(b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'COVID'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User closed query 'Per DM CLR: Please note, 200/250 mg/mL is a concentration, rather than dosage. Please update the Con Med entry to list the specific dose and unit (e.g. 100 mg, etc) within the DOSE and UNIT fields and provide the concentration in the Con Med name since this medication is available in more than one concentration/strength.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 03:49:02
Query 'Per DM CLR: Please note, 200/250 mg/mL is a concentration, rather than dosage. Please update the Con Med entry to list the specific dose and unit (e.g. 100 mg, etc) within the DOSE and UNIT fields and provide the concentration in the Con Med name since this medication is available in more than one concentration/strength.' answered with 'Information transcribed directly from source. Dosage was re-confirmed.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 18:03:46
User opened query 'Per DM CLR: Please note, 200/250 mg/mL is a concentration, rather than dosage. Please update the Con Med entry to list the specific dose and unit (e.g. 100 mg, etc) within the DOSE and UNIT fields and provide the concentration in the Con Med name since this medication is available in more than one concentration/strength.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:46:36
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '200/250'	(b) (4), (b) (6)	08 Jan 2021 19:12:01



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg/mL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	11 Feb 2021 22:27:41
reason for change: Per Query Resolution	(b) (4), (b) (6)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 19:12:01

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:11:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:41:00
Query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:27:46
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:27:41
User opened query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:31:29
User entered 'injection'	(b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User entered empty.	System	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User entered empty.	System	08 Jan 2021 19:12:01

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:56
User entered empty.	System	08 Jan 2021 19:12:01

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:50:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:50:41
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:11:20
Data point term sent to Coder	System	11 Feb 2021 22:28:31
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:28:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:28:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Jan 2021 00:28:45
Data point term sent to Coder	System	08 Jan 2021 19:15:04
User entered 'Remdesivir (VEKLURY) 100 mg in NS 250 mL'	(b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'COVID'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User closed query 'Per DM CLR: Please note, 100/250 mg/mL is a concentration, rather than dosage. Please update the Con Med entry to list the specific dose and unit (e.g. 100 mg, etc) within the DOSE and UNIT fields and provide the concentration in the Con Med name since this medication is available in more than one concentration/strength.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 03:49:21
Query 'Per DM CLR: Please note, 100/250 mg/mL is a concentration, rather than dosage. Please update the Con Med entry to list the specific dose and unit (e.g. 100 mg, etc) within the DOSE and UNIT fields and provide the concentration in the Con Med name since this medication is available in more than one concentration/strength.' answered with 'Information transcribed directly from source. Dosage was re-confirmed.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 18:04:07
User opened query 'Per DM CLR: Please note, 100/250 mg/mL is a concentration, rather than dosage. Please update the Con Med entry to list the specific dose and unit (e.g. 100 mg, etc) within the DOSE and UNIT fields and provide the concentration in the Con Med name since this medication is available in more than one concentration/strength.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:46:45
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '100/250'	(b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg/mL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	11 Feb 2021 22:28:04
reason for change: Per Query Resolution	(b) (4), (b) (6)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 19:14:06

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:11:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:41:23
Query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:28:09
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:28:04
User opened query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:36:27
User entered 'injection'	(b) (4), (b) (6)	08 Jan 2021 19:14:06



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User entered '1'	System	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User entered '1'	System	08 Jan 2021 19:14:06

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:52:59
User entered '804 (804)'	System	08 Jan 2021 19:14:06



US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:57
Data point term sent to Coder	System	11 Feb 2021 22:28:31
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:28:27
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:45
Data point term sent to Coder	System	08 Jan 2021 19:15:04
User entered 'Dexamethasone PF (DECADRON PF)'	(b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'COVID'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	11 Feb 2021 22:28:27
reason for change: Per Query Resolution	(b) (4), (b) (6)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 19:14:59

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:11:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:42:01
Query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:28:33
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:28:27
User opened query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:39:40
User entered 'injection'	(b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User entered empty.	System	08 Jan 2021 19:14:59



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User entered empty.	System	08 Jan 2021 19:14:59

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:05
User entered empty.	System	08 Jan 2021 19:14:59

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:20:58
Data point term sent to Coder	System	11 Feb 2021 22:29:32
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:28:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:52:46
Data point term sent to Coder	System	08 Jan 2021 19:17:04
User entered 'Dexamethasone PF (DECADRON PF)'	(b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'COVID'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '6'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 24 HOURS SCHEDULED'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:28:50
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 19:16:34

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:11:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:42:33
Query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:28:55
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:28:50
User opened query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:41:29
User entered 'injection'	(b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User entered empty.	System	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User entered empty.	System	08 Jan 2021 19:16:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:08
User entered empty.	System	08 Jan 2021 19:16:34

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:58:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:58:50
Data point term sent to Coder	System	08 Jan 2021 19:18:06
User entered 'Famotidine (PEPCID) tablet 20 mg'	(b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:42:27
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' answered with 'This medication was taken during subject's hospitalization. Please see "Media" section in source for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:29:10
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:47:07
User entered 'GERD'	(b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User entered '2'	System	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User entered '1'	System	08 Jan 2021 19:17:54

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:12
User entered '804 (804)'	System	08 Jan 2021 19:17:54

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
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 HFA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:30:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:30:48
Data point term sent to Coder	System	08 Jan 2021 19:20:07
User entered 'Albuterol HFA (PROVENTIL, VENTOLIN, PROAIR) inhaler (non-vented)'	(b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13



US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no DYSPNEA recorded in Symptom Tracker and AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:42:50
Query 'Per DM CLR: Please note there is no DYSPNEA recorded in Symptom Tracker and AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify.' answered with 'This medication was taken during subject's hospitalization. Please see "Media" section in source for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:29:29
User opened query 'Per DM CLR: Please note there is no DYSPNEA recorded in Symptom Tracker and AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:56:09
User entered 'Dyspnea'	(b) (4), (b) (6)	08 Jan 2021 19:19:13

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:11:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count and consider to enter one medication per log line as appropriate. Update all applicable eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:43:36
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count and consider to enter one medication per log line as appropriate. Update all applicable eCRFs as appropriate.' answered with '2 puffs is the dosage amount per source.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:29:46
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count and consider to enter one medication per log line as appropriate. Update all applicable eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 06:58:07
User entered '2'	(b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 6 HOURS PRN'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User entered empty.	System	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User entered empty.	System	08 Jan 2021 19:19:13

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:21
User entered empty.	System	08 Jan 2021 19:19:13



US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 19:22:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 19:22:42
Data point term sent to Coder	System	08 Jan 2021 19:21:07
User entered 'Benzonatate (TESSALON)'	(b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Cough'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '100'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User entered '3'	System	08 Jan 2021 19:20:22



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User entered '1'	System	08 Jan 2021 19:20:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:23
User entered '804 (804)'	System	08 Jan 2021 19:20:22

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE, PRODUCTSYNONYM: PHENERGAN WITH CODEINE [CODEINE PHOSPHATE;PROMETHAZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Jan 2021 00:26:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	09 Jan 2021 00:26:45
Data point term sent to Coder	System	08 Jan 2021 19:25:11
User entered 'Promethazine-codeine (PHENERGAN with CODEINE) 6.25-10 MG/5ML syrup 5 mL'	(b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Cough'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '6.25-10/5'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg/mL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 4 HOURS PRN'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User entered empty.	System	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User entered empty.	System	08 Jan 2021 19:24:25

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:28
User entered empty.	System	08 Jan 2021 19:24:25

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 22:49:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 22:49:45
Data point term sent to Coder	System	08 Jan 2021 19:27:12
User entered 'Acetaminophen (TYLENOL)'	(b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Fever relief'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '650'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 6 HOURS PRN'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User entered empty.	System	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User entered empty.	System	08 Jan 2021 19:26:22

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:32
User entered empty.	System	08 Jan 2021 19:26:22

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:42:54
Data point term sent to Coder	System	11 Feb 2021 22:30:32
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:30:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:57:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:57:45
Data point term sent to Coder	System	08 Jan 2021 19:28:13
User entered 'Enoxaparin (LOVENOX)'	(b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Prevention of CLOTS'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '40'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 24 HOURS SCHEDULED'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Per Query Resolution	(b) (4) (b) (4), (b) (6)	11 Feb 2021 22:30:06
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 19:27:34

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:11:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:44:45
Query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:30:13
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:30:06
User opened query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:01:22
User entered 'injection'	(b) (4), (b) (6)	08 Jan 2021 19:27:34



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User entered empty.	System	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User entered empty.	System	08 Jan 2021 19:27:34

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (39)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:37
User entered empty.	System	08 Jan 2021 19:27:34



US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:25:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:25:55
Data point term sent to Coder	System	11 Feb 2021 22:31:33
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 22:30:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:50:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:50:48
Data point term sent to Coder	System	08 Jan 2021 19:29:14
User entered 'CefTRIAXone (ROCEPHIN)'	(b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:03:16
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	11 Feb 2021 22:30:26
' answered with 'This medication was taken during subject's hospitalization. Please see "Media" section in source for more details. Thank you.' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	11 Feb 2021 07:02:18
' (Site from DM).		
User entered 'Pneumonia'	(b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'EVERY 24 HOURS INTERVAL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	11 Feb 2021 22:30:39
reason for change: Per Query Resolution	(b) (4), (b) (6)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	08 Jan 2021 19:28:52

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:11:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 03:45:50
Query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:30:49
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 22:30:39
User opened query 'Per DM CLR: Please review and specify the injection administration route for this medication. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:03:12
User entered 'injection'	(b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User entered empty.	System	08 Jan 2021 19:28:52



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User entered empty.	System	08 Jan 2021 19:28:52

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (40)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:43
User entered empty.	System	08 Jan 2021 19:28:52

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Jan 2021 23:45:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	08 Jan 2021 23:45:44
Data point term sent to Coder	System	08 Jan 2021 19:30:14
User entered 'Azithromycin (ZITHROMAX)'	(b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:04:51
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	11 Feb 2021 22:31:03
' answered with 'This medication was taken during subject's hospitalization. Please see "Media" section in source for more details. Thank you.' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	11 Feb 2021 07:03:59
' (Site from DM).		
User entered 'Pneumonia'	(b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '500/250'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg/mL'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User entered empty.	System	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User entered empty.	System	08 Jan 2021 19:30:04

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (41)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:47
User entered empty.	System	08 Jan 2021 19:30:04

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 22:53:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 22:53:54
Data point term sent to Coder	System	25 Jan 2021 22:53:24
Coding entries removed.	(b) (4), (b) (6)	25 Jan 2021 22:52:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 22:51:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 22:51:23
Data point term sent to Coder	System	25 Jan 2021 22:50:22
User entered 'Tylenol'	(b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 08:08:22
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	17 Mar 2021 21:27:55
answered with 'LOW GRADE FEVER OF 99.2 - CAPTURED IN EDIARY THE DAY AFTER IP WAS ADMINISTERED' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:30:15
User closed query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4), (b) (6)	26 Feb 2021 06:50:24
(Site from DM).		
Query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4), (b) (6)	25 Feb 2021 18:27:15
' answered with 'Captured in e-Diary.' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.'	(b) (4), (b) (6)	25 Feb 2021 17:02:37
(Site from DM).		
User signature succeeded.	Bindu Balani (b) (4) (b) (4)	19 Feb 2021 22:11:20

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User entered 'LOW GRADE FEVER OF 99.2 - CAPTURED IN EDIARY the day after IP was administered' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 22:52:51
User entered 'Low grade fever of 99.2 - captured in eDiary on 19/Jan/2021'	(b) (4), (b) (6)	25 Jan 2021 22:50:05



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '500'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:11:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES; however, Start Date (19 JAN 2021) of this Con Med is not within the 7-day reporting of Solicited Adverse Reaction. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 08:08:30
Query 'Per DM CLR: Was this medication taken for solicited event? = YES; however, Start Date (19 JAN 2021) of this Con Med is not within the 7-day reporting of Solicited Adverse Reaction. Review if this should be updated. Else, provide clarification on query response.' answered with 'LOW GRADE FEVER OF 99.2 - CAPTURED IN EDIARY THE DAY AFTER IP WAS ADMINISTERED' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 21:28:48
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES; however, Start Date (19 JAN 2021) of this Con Med is not within the 7-day reporting of Solicited Adverse Reaction. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:29:39
Signature has been broken.	(b) (4), (b) (6)	25 Feb 2021 18:27:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 18:27:23
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User entered empty.	System	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User entered empty.	System	25 Jan 2021 22:50:05

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (42)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:54
User entered empty.	System	25 Jan 2021 22:50:05

US3602074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:11:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:49:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:49:49
Data point term sent to Coder	System	12 Feb 2021 21:34:17
User entered 'Oxygen Supplementation'	(b) (4), (b) (6)	12 Feb 2021 21:33:47



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Due to covid-19 (while being hospitalized)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'unk'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User entered empty.	System	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User entered empty.	System	12 Feb 2021 21:33:47



**US3602074**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (43)**

**Generated On: 10 Jun 2021 09:11:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:53:57
User entered empty.	System	12 Feb 2021 21:33:47

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:11:56**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:46:14
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:20:21
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Dec 2020 19:13:46
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 19:51:46

US3602074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:05:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 15:06:33
User closed query 'Per progress note, CT scan was completed. Please verify CT scan details record data.' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 15:06:31
Signature has been broken.	(b) (4), (b) (6)	08 Mar 2021 19:35:43
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Query 'Per progress note, CT scan was completed. Please verify CT scan details record data.' answered with 'CT documented in error in source per PI. ' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	13 Jan 2021 15:54:17
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 01:06:22
DataPoint Un-verified.	(b) (4), (b) (6)	12 Jan 2021 01:04:14
User entered '14 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Jan 2021 01:04:14
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:52:49
DataPoint Un-verified.	(b) (4), (b) (6)	06 Jan 2021 22:52:47
User opened query 'Per progress note, CT scan was completed. Please verify CT scan details record data.' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 22:52:45
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:20:46
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 19:15:04
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 19:15:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 19:14:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 19:14:27
User entered 'un Dec 2020' (non-conformant).	(b) (4), (b) (6)	18 Dec 2020 19:14:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 19:14:19

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:11:56**

**Procedure/Surgery date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered ' 18 Dec 2020' (non-conformant).	(b) (4), (b) (6)	18 Dec 2020 19:14:19

US3602074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:11:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User closed query 'Confirm if subject had chest x-rays on 12/14/20 and 12/20/20 and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 04:01:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Query 'Confirm if subject had chest x-rays on 12/14/20 and 12/20/20 and update data accordingly.' answered with 'Subject did have x-ray's on 12/14/20 and 12/20/20 per the new data uploaded on EPIC's Media tab. Updated accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:05:09
User opened query 'Confirm if subject had chest x-rays on 12/14/20 and 12/20/20 and update data accordingly.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:17:43
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:20:50
User entered 'Chest X-ray'	(b) (4), (b) (6)	18 Dec 2020 19:14:19

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:20:48
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	18 Dec 2020 19:14:19

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:11:56**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:20:52
User entered empty.	(b) (4), (b) (6)	18 Dec 2020 19:14:19

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:11:56**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:02:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:06:44
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '14 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	12 Jan 2021 01:06:35
User entered '20 Dec 2020'	(b) (4), (b) (6)	12 Jan 2021 01:05:29



**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:02:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:06:47
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Chest X-ray'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:05:29

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:02:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:06:51
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:05:29

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:11:56**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:02:19
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 15:06:54
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:05:29

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:11:56**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:02:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20 Dec 2020'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:06:56

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:02:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Chest x-ray'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:06:56

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:02:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:06:56

**US3602074**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:11:56**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:02:22
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 01:06:56

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07



US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '14/Dec/2020 06:58'	(b) (4) System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:25
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered '1'	(b) (4), (b) (6)	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '18/Dec/2020 17:07'	(b) (4) System	18 Dec 2020 17:07:16

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 14:06:34
User entered 'I'	(b) (4), (b) (6)	18 Dec 2020 17:07:16

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '21/Dec/2020 14:06'	(b) (4) System	21 Dec 2020 14:06:43



US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 15:53:13
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 14:06:43

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '29/Dec/2020 10:53'	(b) (4) System	29 Dec 2020 15:53:27

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
User entered '1'	(b) (4), (b) (6)	29 Dec 2020 15:53:27



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '04/Jan/2021 15:15'	(b) (4) System	04 Jan 2021 15:15:46

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:14:00
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 15:15:46

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '05/Jan/2021 09:14'	(b) (4) System	05 Jan 2021 14:14:11

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 14:14:16
User entered 'I'	(b) (4), (b) (6)	05 Jan 2021 14:14:11

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '05/Jan/2021 10:21'	(b) (4) System	05 Jan 2021 15:21:15

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:21:25
User entered 'I'	(b) (4), (b) (6)	05 Jan 2021 15:21:15

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '06/Jan/2021 10:02'	(b) (4) System	06 Jan 2021 15:02:34

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:02:43
User entered 'I'	(b) (4), (b) (6)	06 Jan 2021 15:02:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07



US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '07/Jan/2021 08:39'	(b) (4) System	07 Jan 2021 13:39:38

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:31:49
User entered 'I'	(b) (4), (b) (6)	07 Jan 2021 13:39:38

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (10)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '12/Jan/2021 14:32'	(b) (4) System	12 Jan 2021 19:32:30

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 19:55:58
User entered 'I'	(b) (4), (b) (6)	12 Jan 2021 19:32:30

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (11)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '20/Jan/2021 19:56'	(b) (4) System	20 Jan 2021 19:56:11



US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:57:24
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 19:56:11

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:11:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (12)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered '11/Feb/2021 09:57'	(b) (4) System	11 Feb 2021 14:57:42

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 09:11:56

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:12:49
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:57:42



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:28
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'USA-US079-2020-MRNA-1273-P301000007'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:31
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:33
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:34
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Yes (Y)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:38
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 15:15:33
Un-reviewed for Safety.	System	30 Dec 2020 22:35:32
User entered 'Yes (Y)'	System	30 Dec 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'No (N)'	System	14 Dec 2020 14:56:34



**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:53
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Bindu'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 22:22:54
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'Balani'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:22:58
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 14:57:59
User entered 'NJ'	System	14 Dec 2020 14:56:34

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 22:21:57
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 17:07:06
User entered 'US'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:11:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '13'	System	26 Apr 2021 16:02:55
User signature succeeded.	Bindu Balani (b) (4)	19 Feb 2021 22:11:20
	(b) (4)	
User entered '12'	System	11 Feb 2021 14:57:42
User entered '11'	System	20 Jan 2021 19:56:11
User entered '10'	System	12 Jan 2021 19:32:30
User entered '9'	System	07 Jan 2021 13:39:38
User entered '8'	System	06 Jan 2021 15:02:34
User entered '7'	System	05 Jan 2021 15:21:15
User entered '6'	System	05 Jan 2021 14:14:11
User entered '5'	System	04 Jan 2021 15:15:46
User entered '4'	System	29 Dec 2020 15:53:27
User entered '3'	System	21 Dec 2020 14:06:43
User entered '2'	System	18 Dec 2020 17:07:16
User entered '1'	System	14 Dec 2020 14:58:07

**US3602074**

**Folder: SAE USA-US079-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (13)**

**Generated On: 10 Jun 2021 09:11:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 00:58:37
User entered '26/Apr/2021 12:02'	System	26 Apr 2021 16:02:55

US3602074

Folder: SAE USA-US079-2020-MRNA-1273-P301000007

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 09:11:56

**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 signature succeeded.	Bindu Balani (b) (4)	27 Apr 2021 03:56:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 00:58:37
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 16:02:55