

US3602154 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:14:33

All time stamps listed in this document are displayed in GMT

**US3602154**

**Form: Participant Creation**

**Data signed: (b) (4) 05 Apr 2021 21:52:50**

**Generated On: 10 Jun 2021 09:14:33**

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[Participant ID](#)

US3602154

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

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**US3602154**

**Folder: Screening**

**Form: Visit Date**

**Data signed:** (b) (4) 05 Apr 2021 21:52:53

**Generated On: 10 Jun 2021 09:14:33**

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Date of Birth (MMM yyyy)	(b) (6) 1978
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	ASIAN (INDIA)
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Apr 2021 21:52:52

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	15 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

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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) 05 Apr 2021 21:52:52

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	14:34 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 14:34
Height ( <i>xxx.x</i> )	71 in
Weight ( <i>xxx.x</i> )	243 lb
BMI ( <i>xxx.x</i> )	33.96249 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Apr 2021 21:52:52

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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**

FINANCIAL (CORPORATE OFFICE)

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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) 05 Apr 2021 21:52:52

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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) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

What was the date of randomization? (dd MMM yyyy) 15 OCT 2020

What was the participant's randomization number? 117160

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) 05 Apr 2021 21:52:53**

**Generated On: 10 Jun 2021 09:14:33**

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) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

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)	15 OCT 2020
Time of assessment (00:00-23:59)	14:34 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 14:34
Temperature (xxx.x)	97.3 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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 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: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	16:30 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 16:30
Temperature (xxx.x)	96.3 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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

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) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

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) 15 OCT 2020

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

Treatment Date and Time (derived) 15 OCT 2020 16:00

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	14:34 (24 HR)
Collection date and time (derived)	15 OCT 2020 14:34

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

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

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

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 09:14:33

**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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 16:37

PC Open Date & Time

15 OCT 2020 16:20

PC Close Date & Time

15 OCT 2020 18:50

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

**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	15 OCT 2020 20:51
PC Open Date & Time	15 OCT 2020 19:45
PC Close Date & Time	16 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:14:33

**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

95.7 °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

16 OCT 2020 22:59

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:14:33

**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

97.6 °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

17 OCT 2020 23:24

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 22:51

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:14:33

**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

96.7 °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

19 OCT 2020 22:30

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:14:33

**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

98.7 °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

21 OCT 2020 10:20

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 05:59

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

**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

15 OCT 2020 16:38

PC Open Date & Time

15 OCT 2020 16:20

PC Close Date & Time

15 OCT 2020 18:50

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

**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

15 OCT 2020 20:52

PC Open Date & Time

15 OCT 2020 19:45

PC Close Date & Time

16 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:14:33

**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

16 OCT 2020 23:00

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59



US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:14:33

**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

17 OCT 2020 23:24

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:14:33

**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

18 OCT 2020 22:51

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:14:33

**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

19 OCT 2020 22:30

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:14:33

**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

21 OCT 2020 10:20

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:14:33

**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

22 OCT 2020 06:00

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

**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 ☐

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 16:38
PC Open Date & Time	15 OCT 2020 16:20
PC Close Date & Time	15 OCT 2020 18:50

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

**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 ☐



US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 20:52
PC Open Date & Time	15 OCT 2020 19:45
PC Close Date & Time	16 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:14:33

**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 ☒

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EAB) (1725)

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 23:01
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:14:33

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 ☒

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 23:24
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:14:33

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 ☒

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 22:51
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:14:33

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 ☒



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 22:30
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:14:33

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  
EAB) (1725)

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**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

		Yes <input type="checkbox"/>
PC Time stamp	21 OCT 2020 10:21	
PC Open Date & Time	20 OCT 2020 12:00	
PC Close Date & Time	21 OCT 2020 11:59	

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:14:33

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 ☒

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 06:00
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3602154

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3602154

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3602154

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602154

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3602154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

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)	12 NOV 2020
Time of assessment (00:00-23:59)	13:35 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 13:35
Temperature (xxx.x)	96.9 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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3602154

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

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)	12 NOV 2020
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 15:10
Temperature (xxx.x)	97.5 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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3602154

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3602154

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

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) 12 NOV 2020

What was the treatment time? (00:00-23:59) 14:40 (24 HR)

Treatment Date and Time (derived) 12 NOV 2020 14:40

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



US3602154

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 NOV 2020
Collection time (00:00-23:59)	13:35 (24 HR)
Collection date and time (derived)	12 NOV 2020 13:35

US3602154

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Collection date (dd MMM yyyy)			12 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:35	12 NOV 2020 13:35
Nasopharyngeal Swab 2	No		

US3602154

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 NOV 2020 15:14

PC Open Date & Time

12 NOV 2020 15:00

PC Close Date & Time

12 NOV 2020 17:30

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	12 NOV 2020 19:50
PC Open Date & Time	12 NOV 2020 18:25
PC Close Date & Time	13 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:14:33

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:14:33

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 NOV 2020 12:00

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:14:33

**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

15 NOV 2020 12:47

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59



US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:14:33

**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

97.8 °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

16 NOV 2020 12:27

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:14:33

**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

97.6 °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

17 NOV 2020 12:36

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 NOV 2020 12:43

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

**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

12 NOV 2020 15:14

PC Open Date & Time

12 NOV 2020 15:00

PC Close Date & Time

12 NOV 2020 17:30

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

**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

12 NOV 2020 19:50

PC Open Date & Time

12 NOV 2020 18:25

PC Close Date & Time

13 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:14:33

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:14:33

**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

14 NOV 2020 12:00

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:14:33

**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

15 NOV 2020 12:47

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59



US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:14:33

**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

16 NOV 2020 12:27

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:14:33

**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

17 NOV 2020 12:36

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:14:33

**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

18 NOV 2020 12:43

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

**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 ☐

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

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

No ☒

Yes ☐

PC Time stamp	12 NOV 2020 15:15
PC Open Date & Time	12 NOV 2020 15:00
PC Close Date & Time	12 NOV 2020 17:30

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

**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 ☐

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

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

No ☒

Yes ☐

PC Time stamp	12 NOV 2020 19:51
PC Open Date & Time	12 NOV 2020 18:25
PC Close Date & Time	13 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:14:33

**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 ☐



US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:14:33

Yes ☐

PC Time stamp

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:14:33

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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**US3602154**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:14:33**

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

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:14:33

**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 ☒

**US3602154**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:14:33**

Yes <input type="checkbox"/>	
PC Time stamp	15 NOV 2020 12:47
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:14:33

**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 ☒

**US3602154**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:14:33**

Yes <input type="checkbox"/>	
PC Time stamp	16 NOV 2020 12:27
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:14:33

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 ☒



**US3602154**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:14:33**

Yes <input type="checkbox"/>	
PC Time stamp	17 NOV 2020 12:37
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:14:33

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 ☒

**US3602154**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 09:14:33**

Yes <input type="checkbox"/>	
PC Time stamp	18 NOV 2020 12:43
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3602154

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602154

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602154

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3602154

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Data signed:** (b) (4) 05 Apr 2021 21:52:53

**Generated On: 10 Jun 2021 09:14:33**

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	VISIT3

US3602154

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 DEC 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	10 DEC 2020 13:40
Temperature (xxx.x)	97.4 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602154

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 DEC 2020

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

US3602154

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 DEC 2020
Collection time (00:00-23:59)	14:05 (24 HR)
Collection date and time (derived)	10 DEC 2020 14:05

US3602154

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:53

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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	12 DEC 2020 00:02:00
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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	23 DEC 2020 12:43:27
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59



US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 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 DEC 2020 08:49:00
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 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	18 JAN 2021 12:05:26
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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

23 JAN 2021 00:14:00

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 12:00:35

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59



US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 FEB 2021 00:14:17
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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	13 FEB 2021 00:31:05
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 12:00:26

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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

27 FEB 2021 15:27:49

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 MAR 2021 00:03:02
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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

15 MAR 2021 11:47:40

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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

22 MAR 2021 12:01:17

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 12:24:33

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59



US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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

07 APR 2021 08:02:45

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 10:15:17

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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

19 APR 2021 17:27:20

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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

28 APR 2021 00:02:44

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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

01 MAY 2021 01:40:52

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 <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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 MAY 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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23 JUN 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 271

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	17 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 <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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 299

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	21 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2021 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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="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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 <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"/>



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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06 OCT 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 <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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 NOV 2021 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 <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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	18 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 481

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	05 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2022 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 <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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAR 2022 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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="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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	16 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 APR 2022 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	18 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUN 2022 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 <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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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03 AUG 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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="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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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="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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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°F/38°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"/>



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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="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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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 <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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	15 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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"/>

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	22 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2022 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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](#)

12 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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 ☐



**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 NOV 2022 23:59
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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**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°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 ☐

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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07 DEC 2022 23:59

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US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	10 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2022 23:59

US3602154

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:33

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

**US3602154**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

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

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[Patient Cloud Close Date & Time](#)

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21 DEC 2022 23:59

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**US3602154**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:14:33**

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 15:28:02



US3602154

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602154

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

DAY 119 FEB 2, 2021 - SAFETY  
CALL OVERLAPS WITH OL DAY  
1 VISIT WHICH TOOK PLACE ON  
2/9/2021. AS PER PROTOCOL,  
NO ADDITIONAL SAFETY CALL  
WAS REQUIRED.

US3602154

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 MAR 2021

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

Comments SUBJECT VISITED STUDY SITE  
FOR OL DOSE 2/D29  
APPOINTMENT ON  
9/MARCH/2021. HIS SCHEDULED  
DAY 149 SC--SCHEDULED FOR  
12/MARCH/21 OVERLAPS WITH  
THIS ENCOUNTER. WILL  
CONTINUE TO FOLLOW  
APPROPRIATELY.

*If Contact Not Made, please provide Comments*

US3602154

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 02:39:00

Generated On: 10 Jun 2021 09:14:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 APR 2021

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

Comments PART B: OLD-57 VISIT IS  
COMBINED WITH PART A:  
If Contact Not Made, please provide Comments SAFETY CALL #179

US3602154

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 02:39:00

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3602154**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3602154

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:33

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

US3602154

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:33

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.*

**US3602154**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

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

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

**US3602154**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID-19 Contact**

**Data signed: (b) (4) 05 Apr 2021 21:52:51**

**Generated On: 10 Jun 2021 09:14:33**

Date of Contact	7 JAN 2021
Time of Contact	22:04
Date and Time of Contact (derived)	7 JAN 2021 22:04
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input 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>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input 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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Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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 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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input 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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Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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"/>

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Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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 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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.8 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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Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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"/>

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Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.6 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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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"/>

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Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

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Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 JAN 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.7 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 07 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 JAN 2021
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	96.9 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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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"/>

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Date of Visit	8 JAN 2021
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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	8 JAN 2021
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)	0

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

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

**Data signed: (b) (4) 05 Apr 2021 21:52:51**

**Generated On: 10 Jun 2021 09:14:33**

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed: (b) (4) 05 Apr 2021 21:52:51**

**Generated On: 10 Jun 2021 09:14:33**

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Data signed:** (b) (4) 05 Apr 2021 21:52:51

**Generated On: 10 Jun 2021 09:14:33**

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3602154

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 JAN 2021
Time of assessment (00:00-23:59)	08:26 (24 HR)
Vital Signs Date and Time (derived)	8 JAN 2021 08:26
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602154

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 JAN 2021

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

**US3602154**

**Folder: Illness Visit Day 1 (1)**

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

**Data signed:** (b) (4) 05 Apr 2021 21:52:51

**Generated On: 10 Jun 2021 09:14:33**

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 JAN 2021

US3602154

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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	UNBLND_DECIDE

US3602154

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Date of updated informed consent ( <i>dd MMM yyyy</i> )	9 FEB 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> )	9 FEB 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

**US3602154**

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

**Form: Vital Signs - Dosing**

**Data signed: (b) (4) 05 Apr 2021 21:52:52**

**Generated On: 10 Jun 2021 09:14:33**

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



US3602154

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

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)	9 FEB 2021
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 15:40
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)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3602154

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

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)	9 FEB 2021
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 16:35
Temperature (xxx.x)	97.4 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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3602154

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3602154

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

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) 9 FEB 2021

What was the treatment time? (00:00-23:59) 16:05 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 16:05

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

US3602154

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 FEB 2021

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

9 FEB 2021 14:40

US3602154

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00 - 23:59)	14:44
Collection Date and Time (derived)	9 FEB 2021 14:44

**US3602154**

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

**Form: Continuing**

**Data signed:** (b) (4) 05 Apr 2021 21:52:52

**Generated On: 10 Jun 2021 09:14:33**

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3602154**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 05 Apr 2021 21:52:52

**Generated On: 10 Jun 2021 09:14:33**

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3602154

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

**US3602154**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Data signed:** (b) (4) 05 Apr 2021 21:52:51

**Generated On: 10 Jun 2021 09:14:33**

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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	OLD29

US3602154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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 ( <i>dd MMM yyyy</i> )	9 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	14:10 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 14:10
Temperature ( <i>xxx.x</i> )	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 ( <i>xxx</i> )	63 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	69 mmHg
Diastolic Blood Pressure units	MMHG

US3602154

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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)	9 MAR 2021
Time of assessment (00:00-23:59)	16:50 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 16:50
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)	59 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)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3602154

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 MAR 2021

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

US3602154

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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) 9 MAR 2021

What was the treatment time? (00:00-23:59) 16:20 (24 HR)

Treatment Date and Time (derived) 9 MAR 2021 16:20

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

US3602154

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3602154**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 05 Apr 2021 21:52:52

**Generated On: 10 Jun 2021 09:14:33**

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3602154

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602154

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 02:39:00

Generated On: 10 Jun 2021 09:14:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 APR 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

US3602154

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 02:39:00

Generated On: 10 Jun 2021 09:14:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 APR 2021
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 13:40
Temperature (xxx.x)	97.0 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)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3602154

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 02:38:59

Generated On: 10 Jun 2021 09:14:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 APR 2021

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

US3602154

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 02:38:59

Generated On: 10 Jun 2021 09:14:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 APR 2021
Collection time (00:00-23:59)	13:50 (24 HR)
Collection date and time (derived)	13 APR 2021 13:50

US3602154

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 17:46:57

Generated On: 10 Jun 2021 09:14:33

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3602154

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 21:52:50

Generated On: 10 Jun 2021 09:14:33

AEID	USA-US079-2021-MRNA-1273-P30 1000005
Adverse event	NON - CARDIAC CHEST PAIN
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 type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 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)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	27 FEB 2021
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) 05 Apr 2021 21:52:50

Generated On: 10 Jun 2021 09:14:33

Number of Days in ICU	
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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
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	



US3602154

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 21:52:50

Generated On: 10 Jun 2021 09:14:33

---

PT HAD SUDDEN ONSET OF CHEST PAIN AND WENT TO THE HOSPITAL AND WAS GIVEN ASPIRIN WITH RESOLUTION OF THE CHEST PAIN , WORKUP AFTER ( SUBMITTED ) DID NOT REVEAL DEFINITIVE CARDIAC ISSUES AND IS REC TO SEE A CARDIOLOGIST IN THE NEXT WEEK . THE DIFFERENTIAL WAS CARDIAC VERSUS GERD ON DISCHARGE.

---

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

---

US3602154

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 21:52:50

Generated On: 10 Jun 2021 09:14:33

AEID

Adverse event

UPPER RESPIRATORY TRACT  
INFECTION

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)

6 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 JAN 2021

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 ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 21:52:50

Generated On: 10 Jun 2021 09:14:33

Number of Days in ICU	
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 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3602154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

---

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication FOR DIETARY 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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 2018	
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 (2)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Name of Medication DAYQUIL COLD AND FLU  
(ACETAMINOPHEN 325 MG;  
DEXTROMETHORPHAN HBR 10  
MG; PHENYLEPHRINE HCL 5  
MG)

Prophylaxis Yes ☐  
No ☒

Indication COUGH, NASAL CONGESTION,  
AND RUNNY NOSE - CAPTURED  
IN SYMPTOM TRACKER

Dose per administration 325/10/5

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 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 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 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)		10 JAN 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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Name of Medication ROBITUSSIN COUGH+CHEST  
CONGESTION DM  
(DEXTROMETHORPHAN HBR,  
20MG, GUAIFENESIN 200MG  
PER 20ML)

Prophylaxis Yes ☐  
No ☒

Indication COUGH - CAPTURED IN  
SYMPTOM LOG TRACKER

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 ☒

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 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 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)		8 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Name of Medication NYQUIL COLD AND FLU  
(ACETAMINOPHEN 325 MG;  
DEXTROMETHORPHAN HBR 15  
MG; DOXYLAMINE SUCCINATE  
6.25 MG)

Prophylaxis Yes ☐  
No ☒

Indication SINUS/NASAL CONGESTION -  
CAPTURED IN SYMPTOM LOG  
TRACKER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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 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 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)		10 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PREVENTION

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 (5)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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)	27 FEB 2021	
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 (6)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

	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)		27 FEB 2021
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"/>



US3602154

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 21:52:51

Generated On: 10 Jun 2021 09:14:33

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

**US3602154**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 10 Jun 2021 09:14:33**

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

US3602154

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:33

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 ☐

US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

SAEID	USA-US079-2021-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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)	5

US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

SAEID	USA-US079-2021-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	08/MAR/2021 10:23
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

US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

SAEID	USA-US079-2021-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	10/MAR/2021 08:48
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

US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

SAEID	USA-US079-2021-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	15/MAR/2021 10:01
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

US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

SAEID	USA-US079-2021-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	23/MAR/2021 06:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Apr 2021 21:52:52

Generated On: 10 Jun 2021 09:14:33

SAEID	USA-US079-2021-MRNA-1273-P301000005
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 type="radio"/> No <input checked="" 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)	5
Date of submission (Pre-filled from custom function)	23/MAR/2021 11:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3602154 (Prod: Hackensack University Medical Center)

**US3602154**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:14:33**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'US3602154'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:29:05

**US3602154**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:10:07

**US3602154**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:29:06

**US3602154**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:10:07

**US3602154**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered 'SCRN'	System	15 Oct 2020 19:10:07

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered (b) (6) 1978'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:29:06



**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '42'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered 'YEARS'	System	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered '42'	System	15 Oct 2020 19:11:25

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Race has not been provided. Please correct.' (Site from System).	(b) (4) System	15 Oct 2020 21:29:16
User opened query 'Race has not been provided. Please correct.' (Site from System).	System	15 Oct 2020 19:11:08
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:08



**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:29:16
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Asian (India)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	15 Oct 2020 21:29:16
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:14:33**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:08

**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:25

**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered 'Oct 2020'	System	15 Oct 2020 19:11:25



**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered '2020'	System	15 Oct 2020 19:11:25

**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Amendment 4 (4)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:25

**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:25

**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:25

**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:25

**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:11:25

**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:29:06

**US3602154**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:14:33**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered 'I'	System	15 Oct 2020 20:01:37



**US3602154**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:01:37

US3602154

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:14:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 03:20:01
Query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify. ' answered with 'Confirmed on 12/22/2020. Pt has no medical history per EMR' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:14:38
User opened query 'Per CDM: Age of the subject is >25 years. However, no medical history is collected. Please confirm or update as needed, else please clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 07:49:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 21:31:37

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '14:34'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered '15 Oct 2020 14:34'	System	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '71' in	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27
DataPoint set to visible.	System	15 Oct 2020 20:01:37

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '243' lb	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27
DataPoint set to visible.	System	15 Oct 2020 20:01:37



**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered '33.96249'	System	15 Oct 2020 21:34:27
DataPoint set to visible.	System	15 Oct 2020 20:01:37

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered 'kg/m2'	System	15 Oct 2020 21:34:27
DataPoint set to visible.	System	15 Oct 2020 20:01:37

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered 'bpm'	System	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27



**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered 'breaths/min'	System	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered 'mmHg'	System	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User entered 'mmHg'	System	15 Oct 2020 21:34:27

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04

**US3602154**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04

**US3602154**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:31:07



**US3602154**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:31:07

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

US3602154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:33

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47



**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

US3602154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:33

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Financial (corporate office)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47



**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

US3602154

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:33

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 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:20:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:30:47

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:37:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:37:39



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:37:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'VISIT1'	System	15 Oct 2020 21:37:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 19:03:31

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '117160'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 19:03:31

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 19:03:31

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:14:33**

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)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:39:04

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:14:33**

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)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:39:04

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:39:04



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:14:33**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:39:04

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:14:33**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:39:04

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:39:04
DataPoint set to visible.	System	15 Oct 2020 19:11:25

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Oct 2020 21:41:09



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '14:34'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '15 Oct 2020 14:34'	System	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.3' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '83'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'bpm'	System	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'breaths/min'	System	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '126'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '76'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '16:30'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '15 Oct 2020 16:30'	System	15 Oct 2020 21:41:09

US3602154

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
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)	16 Oct 2020 07:27:17
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 per EMR' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 21:41:44
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	15 Oct 2020 21:41:09
User entered '96.3' F	(b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '65'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'bpm'	System	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'breaths/min'	System	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '118'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '79'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:41:09



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	15 Oct 2020 21:41:09

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:37:49

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:37:49

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:02:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:02:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:02:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 20:02:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:02:39



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '16:00'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:02:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '15 Oct 2020 16:00'	System	15 Oct 2020 20:02:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 20:02:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'ONCE'	System	15 Oct 2020 20:02:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 20:02:39

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:38:10

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:38:10

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '14:34'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:38:10



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '15 Oct 2020 14:34'	System	15 Oct 2020 21:38:10

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:14:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:38:35

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Oct 2020 21:38:35

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:38:35

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15:00'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:38:35

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '15 Oct 2020 15:00'	System	15 Oct 2020 21:38:35

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Oct 2020 21:38:35

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:38:35



**US3602154**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:38:35

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered empty.	System	15 Oct 2020 21:38:35

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:42:02

**US3602154**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'I'	System	15 Oct 2020 21:42:02

**US3602154**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:36:51', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b136fee8-93e1-4614-af6f-b6e99c16e4dd' User entered 'Yes (Y)'	System	15 Oct 2020 20:37:12
	System	15 Oct 2020 20:37:12

**US3602154**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:36:58', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b136fee8-93e1-4614-af6f-b6e99c16e4dd' User entered '96.3'	System	15 Oct 2020 20:37:12
	System	15 Oct 2020 20:37:12

**US3602154**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:37:02', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b136fee8-93e1-4614-af6f-b6e99c16e4dd'	System	15 Oct 2020 20:37:12
User entered 'No (N)'	System	15 Oct 2020 20:37:12



**US3602154**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:37:08', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b136fee8-93e1-4614-af6f-b6e99c16e4dd' User entered '15 Oct 2020 16:37'	System	15 Oct 2020 20:37:12
	System	15 Oct 2020 20:37:12

**US3602154**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Oct 2020 16:20'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Oct 2020 18:50'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:50:57', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3641894c-5221-4a38-be9d-3ac80d0ba1f2' User entered 'Yes (Y)'	System	16 Oct 2020 00:51:24
	System	16 Oct 2020 00:51:24

**US3602154**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:51:02', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3641894c-5221-4a38-be9d-3ac80d0ba1f2' User entered '97.9'	System	16 Oct 2020 00:51:24
	System	16 Oct 2020 00:51:24

**US3602154**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:51:08', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3641894c-5221-4a38-be9d-3ac80d0ba1f2'	System	16 Oct 2020 00:51:24
User entered 'No (N)'	System	16 Oct 2020 00:51:24

**US3602154**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:51:21', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3641894c-5221-4a38-be9d-3ac80d0ba1f2' User entered '15 Oct 2020 20:51'	System	16 Oct 2020 00:51:24
	System	16 Oct 2020 00:51:24



**US3602154**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Oct 2020 19:45'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 2'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T22:59:30', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0e9c916f-6a75-4f5c-9284-c06274e51a6f' User entered 'Yes (Y)'	System	17 Oct 2020 02:59:52
	System	17 Oct 2020 02:59:52

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T22:59:36', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0e9c916f-6a75-4f5c-9284-c06274e51a6f' User entered '95.7'	System	17 Oct 2020 02:59:52
	System	17 Oct 2020 02:59:52

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:14:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T22:59:40', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0e9c916f-6a75-4f5c-9284-c06274e51a6f' User entered 'No (N)'	System	17 Oct 2020 02:59:52
	System	17 Oct 2020 02:59:52

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T22:59:48', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0e9c916f-6a75-4f5c-9284-c06274e51a6f' User entered '16 Oct 2020 22:59'	System	17 Oct 2020 02:59:52
	System	17 Oct 2020 02:59:52

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 20:02:39



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 3'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:23:52', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '7c29e233-93fd-4d2d-aa78-1b33da4575c7' User entered 'Yes (Y)'	System	18 Oct 2020 03:24:10
	System	18 Oct 2020 03:24:10

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:02', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '7c29e233-93fd-4d2d-aa78-1b33da4575c7' User entered '97.6'	System	18 Oct 2020 03:24:10
	System	18 Oct 2020 03:24:10

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:14:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:06', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '7c29e233-93fd-4d2d-aa78-1b33da4575c7' User entered 'No (N)'	System	18 Oct 2020 03:24:10
	System	18 Oct 2020 03:24:10

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:08', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '7c29e233-93fd-4d2d-aa78-1b33da4575c7' User entered '17 Oct 2020 23:24'	System	18 Oct 2020 03:24:10
	System	18 Oct 2020 03:24:10

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 20:02:39



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 4'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:01', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2cd6ab46-464b-41dc-8385-838503b40594' User entered 'Yes (Y)'	System	19 Oct 2020 02:51:16
	System	19 Oct 2020 02:51:16

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:07', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2cd6ab46-464b-41dc-8385-838503b40594' User entered '98.3'	System	19 Oct 2020 02:51:16
	System	19 Oct 2020 02:51:16

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:14:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:11', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2cd6ab46-464b-41dc-8385-838503b40594'	System	19 Oct 2020 02:51:16
User entered 'No (N)'	System	19 Oct 2020 02:51:16

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:14', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2cd6ab46-464b-41dc-8385-838503b40594' User entered '18 Oct 2020 22:51'	System	19 Oct 2020 02:51:16
	System	19 Oct 2020 02:51:16

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 5'	System	15 Oct 2020 20:02:39



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:29:58', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e11eed71-86e4-4635-bd60-d74302a99ff5' User entered 'Yes (Y)'	System	20 Oct 2020 02:30:14
	System	20 Oct 2020 02:30:14

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:04', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e11eed71-86e4-4635-bd60-d74302a99ff5' User entered '96.7'	System	20 Oct 2020 02:30:14
	System	20 Oct 2020 02:30:14

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:14:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:07', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e11eed71-86e4-4635-bd60-d74302a99ff5' User entered 'No (N)'	System	20 Oct 2020 02:30:14
	System	20 Oct 2020 02:30:14

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:10', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e11eed71-86e4-4635-bd60-d74302a99ff5' User entered '19 Oct 2020 22:30'	System	20 Oct 2020 02:30:14
	System	20 Oct 2020 02:30:14

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 6'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:20:28', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '09427f3e-ed46-4902-b1aa-998436621ffa' User entered 'Yes (Y)'	System	21 Oct 2020 14:20:38
	System	21 Oct 2020 14:20:38



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:20:31', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '09427f3e-ed46-4902-b1aa-998436621ffa' User entered '98.7'	System	21 Oct 2020 14:20:38
	System	21 Oct 2020 14:20:38

US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:14:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:20:35', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '09427f3e-ed46-4902-b1aa-998436621ffa' User entered 'No (N)'	System	21 Oct 2020 14:20:38
	System	21 Oct 2020 14:20:38

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:20:37', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '09427f3e-ed46-4902-b1aa-998436621ffa' User entered '21 Oct 2020 10:20'	System	21 Oct 2020 14:20:38
	System	21 Oct 2020 14:20:38

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 7'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T05:59:32', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'ad086d87-6600-4fc7-bc02-993bd2012f8c' User entered 'Yes (Y)'	System	22 Oct 2020 09:59:53
	System	22 Oct 2020 09:59:53

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T05:59:41', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'ad086d87-6600-4fc7-bc02-993bd2012f8c' User entered '98.5'	System	22 Oct 2020 09:59:53
	System	22 Oct 2020 09:59:53



US3602154

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:14:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T05:59:45', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'ad086d87-6600-4fc7-bc02-993bd2012f8c' User entered 'No (N)'	System	22 Oct 2020 09:59:53
	System	22 Oct 2020 09:59:53

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T05:59:48', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'ad086d87-6600-4fc7-bc02-993bd2012f8c' User entered '22 Oct 2020 05:59'	System	22 Oct 2020 09:59:53
	System	22 Oct 2020 09:59:53

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 20:02:39

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:37:20', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '15f7de4f-eaf3-464c-adeb-3c2143cba2f6'	System	15 Oct 2020 20:38:08
User entered 'None (1)'	System	15 Oct 2020 20:38:08

**US3602154**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:37:52', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '15f7de4f-eaf3-464c-adeb-3c2143cba2f6'	System	15 Oct 2020 20:38:08
User entered 'No (N)'	System	15 Oct 2020 20:38:08

**US3602154**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:37:55', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '15f7de4f-eaf3-464c-adeb-3c2143cba2f6'	System	15 Oct 2020 20:38:08
User entered 'No (N)'	System	15 Oct 2020 20:38:08



US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:04', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '15f7de4f-eaf3-464c-adeb-3c2143cba2f6'	System	15 Oct 2020 20:38:08
User entered 'None (1)'	System	15 Oct 2020 20:38:08

**US3602154**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:06', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '15f7de4f-eaf3-464c-adeb-3c2143cba2f6' User entered '15 Oct 2020 16:38'	System	15 Oct 2020 20:38:08
	System	15 Oct 2020 20:38:08

**US3602154**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Oct 2020 16:20'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Oct 2020 18:50'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 20:02:39

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:51:33', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5014a43f-299d-4f11-8ce2-ff0516204850' User entered 'None (1)'	System	16 Oct 2020 00:52:06
	System	16 Oct 2020 00:52:06

**US3602154**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:51:41', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5014a43f-299d-4f11-8ce2-ff0516204850' User entered 'No (N)'	System	16 Oct 2020 00:52:06
	System	16 Oct 2020 00:52:06

**US3602154**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:51:47', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5014a43f-299d-4f11-8ce2-ff0516204850' User entered 'No (N)'	System	16 Oct 2020 00:52:06
	System	16 Oct 2020 00:52:06



US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:51:58', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5014a43f-299d-4f11-8ce2-ff0516204850'	System	16 Oct 2020 00:52:06
User entered 'None (1)'	System	16 Oct 2020 00:52:06

**US3602154**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:52:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5014a43f-299d-4f11-8ce2-ff0516204850' User entered '15 Oct 2020 20:52'	System	16 Oct 2020 00:52:06
	System	16 Oct 2020 00:52:06

**US3602154**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Oct 2020 19:45'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 2'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T22:59:59', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5aa52767-7594-4896-87d3-b54755a582d3' User entered 'None (1)'	System	17 Oct 2020 03:00:26
	System	17 Oct 2020 03:00:26

**US3602154**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:00:03', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5aa52767-7594-4896-87d3-b54755a582d3' User entered 'No (N)'	System	17 Oct 2020 03:00:26
	System	17 Oct 2020 03:00:26

**US3602154**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:00:10', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5aa52767-7594-4896-87d3-b54755a582d3'	System	17 Oct 2020 03:00:26
User entered 'No (N)'	System	17 Oct 2020 03:00:26



US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:00:20', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5aa52767-7594-4896-87d3-b54755a582d3'	System	17 Oct 2020 03:00:26
User entered 'None (1)'	System	17 Oct 2020 03:00:26

**US3602154**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:00:22', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '5aa52767-7594-4896-87d3-b54755a582d3' User entered '16 Oct 2020 23:00'	System	17 Oct 2020 03:00:26
	System	17 Oct 2020 03:00:26

**US3602154**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 3'	System	15 Oct 2020 20:02:39

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:13', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '21b064ae-9ef3-45aa-aaee-964359fea4be' User entered 'None (1)'	System	18 Oct 2020 03:24:33
	System	18 Oct 2020 03:24:33

**US3602154**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:17', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '21b064ae-9ef3-45aa-aaee-964359fea4be' User entered 'No (N)'	System	18 Oct 2020 03:24:33
	System	18 Oct 2020 03:24:33

**US3602154**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:21', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '21b064ae-9ef3-45aa-aaee-964359fea4be' User entered 'No (N)'	System	18 Oct 2020 03:24:33
	System	18 Oct 2020 03:24:33



US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:28', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '21b064ae-9ef3-45aa-aaee-964359fea4be' User entered 'None (1)'	System	18 Oct 2020 03:24:33
	System	18 Oct 2020 03:24:33

**US3602154**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:30', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '21b064ae-9ef3-45aa-aaee-964359fea4be' User entered '17 Oct 2020 23:24'	System	18 Oct 2020 03:24:33
	System	18 Oct 2020 03:24:33

**US3602154**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 4'	System	15 Oct 2020 20:02:39

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:19', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f63e157a-272e-43f5-80e6-cb44bbb75629' User entered 'None (1)'	System	19 Oct 2020 02:51:37
	System	19 Oct 2020 02:51:37

**US3602154**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:23', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f63e157a-272e-43f5-80e6-cb44bbb75629' User entered 'No (N)'	System	19 Oct 2020 02:51:37
	System	19 Oct 2020 02:51:37

**US3602154**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:27', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f63e157a-272e-43f5-80e6-cb44bbb75629' User entered 'No (N)'	System	19 Oct 2020 02:51:37
	System	19 Oct 2020 02:51:37



US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:30', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f63e157a-272e-43f5-80e6-cb44bbb75629' User entered 'None (1)'	System	19 Oct 2020 02:51:37
	System	19 Oct 2020 02:51:37

**US3602154**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:32', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f63e157a-272e-43f5-80e6-cb44bbb75629' User entered '18 Oct 2020 22:51'	System	19 Oct 2020 02:51:37
	System	19 Oct 2020 02:51:37

**US3602154**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 5'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:13', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'a7f1b8d6-c750-43aa-bfe8-ba2704566992'	System	20 Oct 2020 02:30:37
User entered 'None (1)'	System	20 Oct 2020 02:30:37

**US3602154**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:16', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'a7f1b8d6-c750-43aa-bfe8-ba2704566992'	System	20 Oct 2020 02:30:37
User entered 'No (N)'	System	20 Oct 2020 02:30:37

**US3602154**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:19', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'a7f1b8d6-c750-43aa-bfe8-ba2704566992'	System	20 Oct 2020 02:30:37
User entered 'No (N)'	System	20 Oct 2020 02:30:37



US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:26', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'a7f1b8d6-c750-43aa-bfe8-ba2704566992'	System	20 Oct 2020 02:30:37
User entered 'None (1)'	System	20 Oct 2020 02:30:37

**US3602154**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:36', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'a7f1b8d6-c750-43aa-bfe8-ba2704566992' User entered '19 Oct 2020 22:30'	System	20 Oct 2020 02:30:37
	System	20 Oct 2020 02:30:37

**US3602154**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 6'	System	15 Oct 2020 20:02:39

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:20:41', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '85f62a67-e591-41e5-862b-b57410ee7711' User entered 'None (1)'	System	21 Oct 2020 14:20:59
	System	21 Oct 2020 14:20:59

**US3602154**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:20:44', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '85f62a67-e591-41e5-862b-b57410ee7711' User entered 'No (N)'	System	21 Oct 2020 14:20:59
	System	21 Oct 2020 14:20:59

**US3602154**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:20:47', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '85f62a67-e591-41e5-862b-b57410ee7711' User entered 'No (N)'	System	21 Oct 2020 14:20:59
	System	21 Oct 2020 14:20:59



US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:20:49', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '85f62a67-e591-41e5-862b-b57410ee7711' User entered 'None (1)'	System	21 Oct 2020 14:20:59
	System	21 Oct 2020 14:20:59

**US3602154**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:20:55', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '85f62a67-e591-41e5-862b-b57410ee7711' User entered '21 Oct 2020 10:20'	System	21 Oct 2020 14:20:59
	System	21 Oct 2020 14:20:59

**US3602154**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 7'	System	15 Oct 2020 20:02:39

US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T05:59:54', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3c4b4079-43db-4083-b8b1-4a2711cd5635'	System	22 Oct 2020 10:00:10
User entered 'None (1)'	System	22 Oct 2020 10:00:10

**US3602154**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T05:59:57', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3c4b4079-43db-4083-b8b1-4a2711cd5635'	System	22 Oct 2020 10:00:10
User entered 'No (N)'	System	22 Oct 2020 10:00:10

**US3602154**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3c4b4079-43db-4083-b8b1-4a2711cd5635'	System	22 Oct 2020 10:00:10
User entered 'No (N)'	System	22 Oct 2020 10:00:10



US3602154

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:02', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3c4b4079-43db-4083-b8b1-4a2711cd5635'	System	22 Oct 2020 10:00:10
User entered 'None (1)'	System	22 Oct 2020 10:00:10

**US3602154**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:05', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3c4b4079-43db-4083-b8b1-4a2711cd5635'	System	22 Oct 2020 10:00:10
User entered '22 Oct 2020 06:00'	System	22 Oct 2020 10:00:10

**US3602154**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:11', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '87eee32c-92a5-4478-ab93-411ad7afd897' User entered 'None (0)'	System	15 Oct 2020 20:38:40
	System	15 Oct 2020 20:38:40

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:14', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '87eee32c-92a5-4478-ab93-411ad7afd897' User entered 'None (0)'	System	15 Oct 2020 20:38:40
	System	15 Oct 2020 20:38:40

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:16', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '87eee32c-92a5-4478-ab93-411ad7afd897' User entered 'None (0)'	System	15 Oct 2020 20:38:40
	System	15 Oct 2020 20:38:40



**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:20', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '87eee32c-92a5-4478-ab93-411ad7afd897' User entered 'None (0)'	System	15 Oct 2020 20:38:40
	System	15 Oct 2020 20:38:40

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:23', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '87eee32c-92a5-4478-ab93-411ad7afd897' User entered 'None (0)'	System	15 Oct 2020 20:38:40
	System	15 Oct 2020 20:38:40

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:28', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '87eee32c-92a5-4478-ab93-411ad7afd897' User entered 'None (0)'	System	15 Oct 2020 20:38:40
	System	15 Oct 2020 20:38:40

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:35', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '87eee32c-92a5-4478-ab93-411ad7afd897' User entered 'No (N)'	System	15 Oct 2020 20:38:40
	System	15 Oct 2020 20:38:40

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T16:38:38', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '87eee32c-92a5-4478-ab93-411ad7afd897' User entered '15 Oct 2020 16:38'	System	15 Oct 2020 20:38:40
	System	15 Oct 2020 20:38:40

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Oct 2020 16:20'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Oct 2020 18:50'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 20:02:39



**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:52:05', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29d318af-afcc-45da-bd25-3bcb14d855c3' User entered 'None (0)'	System	16 Oct 2020 00:52:35
	System	16 Oct 2020 00:52:35

**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:52:09', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29d318af-afcc-45da-bd25-3bcb14d855c3' User entered 'None (0)'	System	16 Oct 2020 00:52:35
	System	16 Oct 2020 00:52:35

**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:52:12', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29d318af-afcc-45da-bd25-3bcb14d855c3' User entered 'None (0)'	System	16 Oct 2020 00:52:35
	System	16 Oct 2020 00:52:35

**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:52:18', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29d318af-afcc-45da-bd25-3bcb14d855c3' User entered 'None (0)'	System	16 Oct 2020 00:52:35
	System	16 Oct 2020 00:52:35

**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:52:21', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29d318af-afcc-45da-bd25-3bcb14d855c3' User entered 'None (0)'	System	16 Oct 2020 00:52:35
	System	16 Oct 2020 00:52:35

**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:52:23', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29d318af-afcc-45da-bd25-3bcb14d855c3' User entered 'None (0)'	System	16 Oct 2020 00:52:35
	System	16 Oct 2020 00:52:35

**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:52:28', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29d318af-afcc-45da-bd25-3bcb14d855c3' User entered 'No (N)'	System	16 Oct 2020 00:52:35
	System	16 Oct 2020 00:52:35

**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-15T20:52:31', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29d318af-afcc-45da-bd25-3bcb14d855c3' User entered '15 Oct 2020 20:52'	System	16 Oct 2020 00:52:35
	System	16 Oct 2020 00:52:35



**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Oct 2020 19:45'	System	15 Oct 2020 20:02:39

**US3602154**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 2'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:00:41', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '64df0c7f-1db1-4bd3-97ca-0e3a4dfe187f' User entered 'None (0)'	System	17 Oct 2020 03:01:18
	System	17 Oct 2020 03:01:18

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:00:44', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '64df0c7f-1db1-4bd3-97ca-0e3a4dfe187f' User entered 'None (0)'	System	17 Oct 2020 03:01:18
	System	17 Oct 2020 03:01:18

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:00:55', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '64df0c7f-1db1-4bd3-97ca-0e3a4dfe187f' User entered 'None (0)'	System	17 Oct 2020 03:01:18
	System	17 Oct 2020 03:01:18

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:00:59', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '64df0c7f-1db1-4bd3-97ca-0e3a4dfe187f' User entered 'None (0)'	System	17 Oct 2020 03:01:18
	System	17 Oct 2020 03:01:18

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:01:02', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '64df0c7f-1db1-4bd3-97ca-0e3a4dfe187f' User entered 'None (0)'	System	17 Oct 2020 03:01:18
	System	17 Oct 2020 03:01:18



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:01:04', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '64df0c7f-1db1-4bd3-97ca-0e3a4dfe187f' User entered 'None (0)'	System	17 Oct 2020 03:01:18
	System	17 Oct 2020 03:01:18

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:01:11', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '64df0c7f-1db1-4bd3-97ca-0e3a4dfe187f' User entered 'No (N)'	System	17 Oct 2020 03:01:18
	System	17 Oct 2020 03:01:18

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-16T23:01:13', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '64df0c7f-1db1-4bd3-97ca-0e3a4dfe187f' User entered '16 Oct 2020 23:01'	System	17 Oct 2020 03:01:18
	System	17 Oct 2020 03:01:18

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 3'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:34', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c1192371-cd2f-4469-8195-17db6998cfef' User entered 'None (0)'	System	18 Oct 2020 03:24:59
	System	18 Oct 2020 03:24:59

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:36', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c1192371-cd2f-4469-8195-17db6998cfef' User entered 'None (0)'	System	18 Oct 2020 03:24:59
	System	18 Oct 2020 03:24:59



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:38', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c1192371-cd2f-4469-8195-17db6998cfef' User entered 'None (0)'	System	18 Oct 2020 03:24:59
	System	18 Oct 2020 03:24:59

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:40', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c1192371-cd2f-4469-8195-17db6998cfef' User entered 'None (0)'	System	18 Oct 2020 03:24:59
	System	18 Oct 2020 03:24:59

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:42', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c1192371-cd2f-4469-8195-17db6998cfef' User entered 'None (0)'	System	18 Oct 2020 03:24:59
	System	18 Oct 2020 03:24:59

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:44', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c1192371-cd2f-4469-8195-17db6998cfef' User entered 'None (0)'	System	18 Oct 2020 03:24:59
	System	18 Oct 2020 03:24:59

US3602154

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:48', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c1192371-cd2f-4469-8195-17db6998cfef' User entered 'No (N)'	System	18 Oct 2020 03:24:59
	System	18 Oct 2020 03:24:59

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-17T23:24:56', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c1192371-cd2f-4469-8195-17db6998cfef' User entered '17 Oct 2020 23:24'	System	18 Oct 2020 03:24:59
	System	18 Oct 2020 03:24:59

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 20:02:39



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 4'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:37', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a5ca8e5-fa2e-4eaa-9b23-446ce1d0f707' User entered 'None (0)'	System	19 Oct 2020 02:51:57
	System	19 Oct 2020 02:51:57

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:39', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a5ca8e5-fa2e-4eaa-9b23-446ce1d0f707' User entered 'None (0)'	System	19 Oct 2020 02:51:57
	System	19 Oct 2020 02:51:57

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:41', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a5ca8e5-fa2e-4eaa-9b23-446ce1d0f707' User entered 'None (0)'	System	19 Oct 2020 02:51:57
	System	19 Oct 2020 02:51:57

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:43', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a5ca8e5-fa2e-4eaa-9b23-446ce1d0f707' User entered 'None (0)'	System	19 Oct 2020 02:51:57
	System	19 Oct 2020 02:51:57

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:45', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a5ca8e5-fa2e-4eaa-9b23-446ce1d0f707' User entered 'None (0)'	System	19 Oct 2020 02:51:57
	System	19 Oct 2020 02:51:57

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:47', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a5ca8e5-fa2e-4eaa-9b23-446ce1d0f707' User entered 'None (0)'	System	19 Oct 2020 02:51:57
	System	19 Oct 2020 02:51:57

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:52', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a5ca8e5-fa2e-4eaa-9b23-446ce1d0f707'	System	19 Oct 2020 02:51:57
User entered 'No (N)'	System	19 Oct 2020 02:51:57



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-18T22:51:54', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a5ca8e5-fa2e-4eaa-9b23-446ce1d0f707' User entered '18 Oct 2020 22:51'	System	19 Oct 2020 02:51:57
	System	19 Oct 2020 02:51:57

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 5'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:40', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6e9056f-8b25-46bd-9830-a00c9afd0019' User entered 'None (0)'	System	20 Oct 2020 02:30:54
	System	20 Oct 2020 02:30:54

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:42', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6e9056f-8b25-46bd-9830-a00c9afd0019' User entered 'None (0)'	System	20 Oct 2020 02:30:54
	System	20 Oct 2020 02:30:54

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:43', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6e9056f-8b25-46bd-9830-a00c9afd0019' User entered 'None (0)'	System	20 Oct 2020 02:30:54
	System	20 Oct 2020 02:30:54

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:45', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6e9056f-8b25-46bd-9830-a00c9afd0019' User entered 'None (0)'	System	20 Oct 2020 02:30:54
	System	20 Oct 2020 02:30:54



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:47', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6e9056f-8b25-46bd-9830-a00c9afd0019' User entered 'None (0)'	System	20 Oct 2020 02:30:54
	System	20 Oct 2020 02:30:54

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:48', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6e9056f-8b25-46bd-9830-a00c9afd0019' User entered 'None (0)'	System	20 Oct 2020 02:30:54
	System	20 Oct 2020 02:30:54

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:51', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6e9056f-8b25-46bd-9830-a00c9afd0019' User entered 'No (N)'	System	20 Oct 2020 02:30:54
	System	20 Oct 2020 02:30:54

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-19T22:30:53', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6e9056f-8b25-46bd-9830-a00c9afd0019' User entered '19 Oct 2020 22:30'	System	20 Oct 2020 02:30:54
	System	20 Oct 2020 02:30:54

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 6'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:21:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a2ba938-cde1-4bf5-85c5-4061edc869db' User entered 'None (0)'	System	21 Oct 2020 14:21:21
	System	21 Oct 2020 14:21:21



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:21:02', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a2ba938-cde1-4bf5-85c5-4061edc869db' User entered 'None (0)'	System	21 Oct 2020 14:21:21
	System	21 Oct 2020 14:21:21

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:21:06', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a2ba938-cde1-4bf5-85c5-4061edc869db' User entered 'None (0)'	System	21 Oct 2020 14:21:21
	System	21 Oct 2020 14:21:21

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:21:08', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a2ba938-cde1-4bf5-85c5-4061edc869db' User entered 'None (0)'	System	21 Oct 2020 14:21:21
	System	21 Oct 2020 14:21:21

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:21:11', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a2ba938-cde1-4bf5-85c5-4061edc869db' User entered 'None (0)'	System	21 Oct 2020 14:21:21
	System	21 Oct 2020 14:21:21

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:21:13', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a2ba938-cde1-4bf5-85c5-4061edc869db' User entered 'None (0)'	System	21 Oct 2020 14:21:21
	System	21 Oct 2020 14:21:21

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:21:17', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a2ba938-cde1-4bf5-85c5-4061edc869db' User entered 'No (N)'	System	21 Oct 2020 14:21:21
	System	21 Oct 2020 14:21:21

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-21T10:21:19', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '1a2ba938-cde1-4bf5-85c5-4061edc869db' User entered '21 Oct 2020 10:21'	System	21 Oct 2020 14:21:21
	System	21 Oct 2020 14:21:21

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 20:02:39



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	15 Oct 2020 20:02:39
User entered 'Day 7'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:10', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c0a3c950-4216-4f40-9c46-695e5688d6ad' User entered 'None (0)'	System	22 Oct 2020 10:00:31
	System	22 Oct 2020 10:00:31

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:12', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c0a3c950-4216-4f40-9c46-695e5688d6ad' User entered 'None (0)'	System	22 Oct 2020 10:00:31
	System	22 Oct 2020 10:00:31

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:14', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c0a3c950-4216-4f40-9c46-695e5688d6ad' User entered 'None (0)'	System	22 Oct 2020 10:00:31
	System	22 Oct 2020 10:00:31

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:16', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c0a3c950-4216-4f40-9c46-695e5688d6ad' User entered 'None (0)'	System	22 Oct 2020 10:00:31
	System	22 Oct 2020 10:00:31

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:19', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c0a3c950-4216-4f40-9c46-695e5688d6ad' User entered 'None (0)'	System	22 Oct 2020 10:00:31
	System	22 Oct 2020 10:00:31

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:21', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c0a3c950-4216-4f40-9c46-695e5688d6ad' User entered 'None (0)'	System	22 Oct 2020 10:00:31
	System	22 Oct 2020 10:00:31



**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:26', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c0a3c950-4216-4f40-9c46-695e5688d6ad' User entered 'No (N)'	System	22 Oct 2020 10:00:31
	System	22 Oct 2020 10:00:31

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-10-22T06:00:28', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'c0a3c950-4216-4f40-9c46-695e5688d6ad' User entered '22 Oct 2020 06:00'	System	22 Oct 2020 10:00:31
	System	22 Oct 2020 10:00:31

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 20:02:39

**US3602154**

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

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

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 20:02:39

**US3602154**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:53:31

**US3602154**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:53:31

**US3602154**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:53:31

**US3602154**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:53:31



**US3602154**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:48:37

**US3602154**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'I'	System	12 Nov 2020 19:48:37

**US3602154**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:54:27

**US3602154**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:54:27

**US3602154**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:54:27

**US3602154**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:54:27

**US3602154**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:49:30

**US3602154**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'I'	System	12 Nov 2020 19:49:30



**US3602154**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:54:59

**US3602154**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '5 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:54:59

**US3602154**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:54:59

**US3602154**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:54:59

**US3602154**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:49:37

**US3602154**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'I'	System	12 Nov 2020 19:49:37

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:45:53

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:45:53



**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:45:53

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'VISIT2'	System	13 Nov 2020 20:45:53

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '13:35'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '12 Nov 2020 13:35'	System	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '96.9' F	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06



**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '90'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'bpm'	System	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '18'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'breaths/min'	System	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '126'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	13 Nov 2020 20:52:06



**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '73'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15:10'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '12 Nov 2020 15:10'	System	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06



**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '69'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'bpm'	System	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '18'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'breaths/min'	System	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '114'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	13 Nov 2020 20:52:06



**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '77'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	13 Nov 2020 20:52:06

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:48:20

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:48:20

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:50:11

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:50:11

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:50:11

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'MRNA-1273 OR PLACEBO'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:50:11

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '14:40'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:50:11

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '12 Nov 2020 14:40'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:50:11

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'ONCE'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'INTRAMUSCULAR'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:48:35

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:48:35



**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '13:35'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:48:35

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '12 Nov 2020 13:35'	System	13 Nov 2020 20:48:35

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:14:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:49:31

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Nov 2020 20:49:31

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:49:31

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '13:35'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:49:31

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '12 Nov 2020 13:35'	System	13 Nov 2020 20:49:31

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Nov 2020 20:49:31



**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:49:31

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:14:33**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:49:31

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered empty.	System	13 Nov 2020 20:49:31

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 20:49:47

**US3602154**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '1'	System	13 Nov 2020 20:49:47

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:14:05', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9fc48d1c-9a69-46b8-9779-dc3c01099908' User entered 'Yes (Y)'	System	12 Nov 2020 20:14:23
	System	12 Nov 2020 20:14:23

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:14:12', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9fc48d1c-9a69-46b8-9779-dc3c01099908' User entered '97.5'	System	12 Nov 2020 20:14:23
	System	12 Nov 2020 20:14:23



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:14:16', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9fc48d1c-9a69-46b8-9779-dc3c01099908' User entered 'No (N)'	System	12 Nov 2020 20:14:23
	System	12 Nov 2020 20:14:23

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:14:19', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9fc48d1c-9a69-46b8-9779-dc3c01099908' User entered '12 Nov 2020 15:14'	System	12 Nov 2020 20:14:23
	System	12 Nov 2020 20:14:23

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '12 Nov 2020 15:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '12 Nov 2020 17:30'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:23', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '96b1e702-f85c-47d3-bfc8-a64a47f3cbd6' User entered 'Yes (Y)'	System	13 Nov 2020 00:50:37
	System	13 Nov 2020 00:50:37

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:27', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '96b1e702-f85c-47d3-bfc8-a64a47f3cbd6' User entered '97.5'	System	13 Nov 2020 00:50:37
	System	13 Nov 2020 00:50:37

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:30', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '96b1e702-f85c-47d3-bfc8-a64a47f3cbd6'	System	13 Nov 2020 00:50:37
User entered 'No (N)'	System	13 Nov 2020 00:50:37



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:33', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '96b1e702-f85c-47d3-bfc8-a64a47f3cbd6'	System	13 Nov 2020 00:50:37
User entered '12 Nov 2020 19:50'	System	13 Nov 2020 00:50:37

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '12 Nov 2020 18:25'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 2'	System	12 Nov 2020 19:50:11

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:14:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:14:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:14:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:14:33

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42



US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:14:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 3'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:13', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '08504832-1279-4d3b-a5c1-a6cfd9629d13' User entered 'Yes (Y)'	System	14 Nov 2020 17:00:28
	System	14 Nov 2020 17:00:28

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:18', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '08504832-1279-4d3b-a5c1-a6cfd9629d13' User entered '98.3'	System	14 Nov 2020 17:00:28
	System	14 Nov 2020 17:00:28

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:21', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '08504832-1279-4d3b-a5c1-a6cfd9629d13' User entered 'No (N)'	System	14 Nov 2020 17:00:28
	System	14 Nov 2020 17:00:28



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:24', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '08504832-1279-4d3b-a5c1-a6cfd9629d13' User entered '14 Nov 2020 12:00'	System	14 Nov 2020 17:00:28
	System	14 Nov 2020 17:00:28

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 4'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:13', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd3d5be7d-c3f3-4beb-8571-cd194ba89ddb' User entered 'Yes (Y)'	System	15 Nov 2020 17:47:24
	System	15 Nov 2020 17:47:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:17', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd3d5be7d-c3f3-4beb-8571-cd194ba89ddb' User entered '97.6'	System	15 Nov 2020 17:47:24
	System	15 Nov 2020 17:47:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**Was any MEDICATION TAKEN today for pain or fever?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:20', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd3d5be7d-c3f3-4beb-8571-cd194ba89ddb' User entered 'No (N)'	System	15 Nov 2020 17:47:24
	System	15 Nov 2020 17:47:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:22', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd3d5be7d-c3f3-4beb-8571-cd194ba89ddb' User entered '15 Nov 2020 12:47'	System	15 Nov 2020 17:47:24
	System	15 Nov 2020 17:47:24



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 5'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:26:54', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'faaa8af0-2bad-4b42-bd9d-6a47ea5da340' User entered 'Yes (Y)'	System	16 Nov 2020 17:27:07
	System	16 Nov 2020 17:27:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:26:59', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'faaa8af0-2bad-4b42-bd9d-6a47ea5da340' User entered '97.8'	System	16 Nov 2020 17:27:07
	System	16 Nov 2020 17:27:07

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:14:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'faaa8af0-2bad-4b42-bd9d-6a47ea5da340'	System	16 Nov 2020 17:27:07
User entered 'No (N)'	System	16 Nov 2020 17:27:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:03', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'faaa8af0-2bad-4b42-bd9d-6a47ea5da340'	System	16 Nov 2020 17:27:07
User entered '16 Nov 2020 12:27'	System	16 Nov 2020 17:27:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 6'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:28', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8c253b9d-24db-427c-bca9-080d067e003c' User entered 'Yes (Y)'	System	17 Nov 2020 17:36:43
	System	17 Nov 2020 17:36:43

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:34', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8c253b9d-24db-427c-bca9-080d067e003c' User entered '97.6'	System	17 Nov 2020 17:36:43
	System	17 Nov 2020 17:36:43

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:14:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:37', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8c253b9d-24db-427c-bca9-080d067e003c' User entered 'No (N)'	System	17 Nov 2020 17:36:43
	System	17 Nov 2020 17:36:43

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:39', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8c253b9d-24db-427c-bca9-080d067e003c' User entered '17 Nov 2020 12:36'	System	17 Nov 2020 17:36:43
	System	17 Nov 2020 17:36:43

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 7'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:05', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '70543350-2395-43fb-8539-adab6f4d5bc3' User entered 'Yes (Y)'	System	18 Nov 2020 17:43:17
	System	18 Nov 2020 17:43:17

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:10', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '70543350-2395-43fb-8539-adab6f4d5bc3' User entered '97.8'	System	18 Nov 2020 17:43:17
	System	18 Nov 2020 17:43:17

US3602154

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:14:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:12', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '70543350-2395-43fb-8539-adab6f4d5bc3'	System	18 Nov 2020 17:43:17
User entered 'No (N)'	System	18 Nov 2020 17:43:17

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:14', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '70543350-2395-43fb-8539-adab6f4d5bc3' User entered '18 Nov 2020 12:43'	System	18 Nov 2020 17:43:17
	System	18 Nov 2020 17:43:17

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 19:50:11



US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:14:26', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4737078-cee7-4181-a2b6-e81da689cb6b' User entered 'None (1)'	System	12 Nov 2020 20:15:00
	System	12 Nov 2020 20:15:00

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:14:50', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4737078-cee7-4181-a2b6-e81da689cb6b' User entered 'No (N)'	System	12 Nov 2020 20:15:00
	System	12 Nov 2020 20:15:00

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:14:53', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4737078-cee7-4181-a2b6-e81da689cb6b' User entered 'No (N)'	System	12 Nov 2020 20:15:00
	System	12 Nov 2020 20:15:00

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:14:55', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4737078-cee7-4181-a2b6-e81da689cb6b' User entered 'None (1)'	System	12 Nov 2020 20:15:00
	System	12 Nov 2020 20:15:00

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:14:58', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4737078-cee7-4181-a2b6-e81da689cb6b' User entered '12 Nov 2020 15:14'	System	12 Nov 2020 20:15:00
	System	12 Nov 2020 20:15:00

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '12 Nov 2020 15:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '12 Nov 2020 17:30'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 19:50:11



US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:36', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6c4fba30-d2b7-47de-8291-c4900db72410' User entered 'None (1)'	System	13 Nov 2020 00:50:48
	System	13 Nov 2020 00:50:48

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:39', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6c4fba30-d2b7-47de-8291-c4900db72410' User entered 'No (N)'	System	13 Nov 2020 00:50:48
	System	13 Nov 2020 00:50:48

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:40', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6c4fba30-d2b7-47de-8291-c4900db72410' User entered 'No (N)'	System	13 Nov 2020 00:50:48
	System	13 Nov 2020 00:50:48

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:42', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6c4fba30-d2b7-47de-8291-c4900db72410' User entered 'None (1)'	System	13 Nov 2020 00:50:48
	System	13 Nov 2020 00:50:48

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:44', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6c4fba30-d2b7-47de-8291-c4900db72410' User entered '12 Nov 2020 19:50'	System	13 Nov 2020 00:50:48
	System	13 Nov 2020 00:50:48

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '12 Nov 2020 18:25'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 2'	System	12 Nov 2020 19:50:11



US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:14:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**Please record - REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:14:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:14:33

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 3'	System	12 Nov 2020 19:50:11

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:27', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '530c7ef9-7cff-4452-a063-3e307ade0ed3' User entered 'None (1)'	System	14 Nov 2020 17:00:37
	System	14 Nov 2020 17:00:37

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:29', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '530c7ef9-7cff-4452-a063-3e307ade0ed3' User entered 'No (N)'	System	14 Nov 2020 17:00:37
	System	14 Nov 2020 17:00:37

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:30', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '530c7ef9-7cff-4452-a063-3e307ade0ed3' User entered 'No (N)'	System	14 Nov 2020 17:00:37
	System	14 Nov 2020 17:00:37

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:32', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '530c7ef9-7cff-4452-a063-3e307ade0ed3' User entered 'None (1)'	System	14 Nov 2020 17:00:37
	System	14 Nov 2020 17:00:37

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:34', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '530c7ef9-7cff-4452-a063-3e307ade0ed3' User entered '14 Nov 2020 12:00'	System	14 Nov 2020 17:00:37
	System	14 Nov 2020 17:00:37

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 4'	System	12 Nov 2020 19:50:11

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:26', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f3d34692-160b-4744-a584-85db03313053'	System	15 Nov 2020 17:47:40
User entered 'None (1)'	System	15 Nov 2020 17:47:40

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:29', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f3d34692-160b-4744-a584-85db03313053'	System	15 Nov 2020 17:47:40
User entered 'No (N)'	System	15 Nov 2020 17:47:40

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:30', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f3d34692-160b-4744-a584-85db03313053'	System	15 Nov 2020 17:47:40
User entered 'No (N)'	System	15 Nov 2020 17:47:40

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:32', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f3d34692-160b-4744-a584-85db03313053'	System	15 Nov 2020 17:47:40
User entered 'None (1)'	System	15 Nov 2020 17:47:40

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:34', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f3d34692-160b-4744-a584-85db03313053' User entered '15 Nov 2020 12:47'	System	15 Nov 2020 17:47:40
	System	15 Nov 2020 17:47:40

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 5'	System	12 Nov 2020 19:50:11

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:06', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd5971e3b-20c1-40df-8dc7-b72247414e79' User entered 'None (1)'	System	16 Nov 2020 17:27:16
	System	16 Nov 2020 17:27:16

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:08', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd5971e3b-20c1-40df-8dc7-b72247414e79' User entered 'No (N)'	System	16 Nov 2020 17:27:16
	System	16 Nov 2020 17:27:16

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:10', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd5971e3b-20c1-40df-8dc7-b72247414e79' User entered 'No (N)'	System	16 Nov 2020 17:27:16
	System	16 Nov 2020 17:27:16

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:11', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd5971e3b-20c1-40df-8dc7-b72247414e79' User entered 'None (1)'	System	16 Nov 2020 17:27:16
	System	16 Nov 2020 17:27:16

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:14', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd5971e3b-20c1-40df-8dc7-b72247414e79' User entered '16 Nov 2020 12:27'	System	16 Nov 2020 17:27:16
	System	16 Nov 2020 17:27:16

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 6'	System	12 Nov 2020 19:50:11

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:42', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b2506ccc-a5cf-4fdd-80b1-9e2a3df4c0ae'	System	17 Nov 2020 17:36:55
User entered 'None (1)'	System	17 Nov 2020 17:36:55

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:44', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b2506ccc-a5cf-4fdd-80b1-9e2a3df4c0ae'	System	17 Nov 2020 17:36:55
User entered 'No (N)'	System	17 Nov 2020 17:36:55

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:45', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b2506ccc-a5cf-4fdd-80b1-9e2a3df4c0ae' User entered 'No (N)'	System	17 Nov 2020 17:36:55
	System	17 Nov 2020 17:36:55

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:47', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b2506ccc-a5cf-4fdd-80b1-9e2a3df4c0ae'	System	17 Nov 2020 17:36:55
User entered 'None (1)'	System	17 Nov 2020 17:36:55

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:49', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b2506ccc-a5cf-4fdd-80b1-9e2a3df4c0ae' User entered '17 Nov 2020 12:36'	System	17 Nov 2020 17:36:55
	System	17 Nov 2020 17:36:55

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 7'	System	12 Nov 2020 19:50:11

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:19', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '78890003-cd0f-4ea7-982c-ebe33a09d457'	System	18 Nov 2020 17:43:31
User entered 'None (1)'	System	18 Nov 2020 17:43:31

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:21', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '78890003-cd0f-4ea7-982c-ebe33a09d457'	System	18 Nov 2020 17:43:31
User entered 'No (N)'	System	18 Nov 2020 17:43:31

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:23', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '78890003-cd0f-4ea7-982c-ebe33a09d457'	System	18 Nov 2020 17:43:31
User entered 'No (N)'	System	18 Nov 2020 17:43:31

US3602154

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:24', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '78890003-cd0f-4ea7-982c-ebe33a09d457' User entered 'None (1)'	System	18 Nov 2020 17:43:31
	System	18 Nov 2020 17:43:31

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:26', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '78890003-cd0f-4ea7-982c-ebe33a09d457' User entered '18 Nov 2020 12:43'	System	18 Nov 2020 17:43:31
	System	18 Nov 2020 17:43:31

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:15:02', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '947fa863-be69-4a33-ad97-f5b9fb0e1a87' User entered 'None (0)'	System	12 Nov 2020 20:15:24
	System	12 Nov 2020 20:15:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:15:04', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '947fa863-be69-4a33-ad97-f5b9fb0e1a87' User entered 'None (0)'	System	12 Nov 2020 20:15:24
	System	12 Nov 2020 20:15:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:15:06', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '947fa863-be69-4a33-ad97-f5b9fb0e1a87' User entered 'None (0)'	System	12 Nov 2020 20:15:24
	System	12 Nov 2020 20:15:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:15:08', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '947fa863-be69-4a33-ad97-f5b9fb0e1a87' User entered 'None (0)'	System	12 Nov 2020 20:15:24
	System	12 Nov 2020 20:15:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:15:10', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '947fa863-be69-4a33-ad97-f5b9fb0e1a87' User entered 'None (0)'	System	12 Nov 2020 20:15:24
	System	12 Nov 2020 20:15:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:15:12', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '947fa863-be69-4a33-ad97-f5b9fb0e1a87' User entered 'None (0)'	System	12 Nov 2020 20:15:24
	System	12 Nov 2020 20:15:24



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:15:14', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '947fa863-be69-4a33-ad97-f5b9fb0e1a87' User entered 'No (N)'	System	12 Nov 2020 20:15:24
	System	12 Nov 2020 20:15:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T15:15:17', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '947fa863-be69-4a33-ad97-f5b9fb0e1a87' User entered '12 Nov 2020 15:15'	System	12 Nov 2020 20:15:24
	System	12 Nov 2020 20:15:24

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '12 Nov 2020 15:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '12 Nov 2020 17:30'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:48', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9f584011-9b2c-49e1-92c2-d5c12abde1dc' User entered 'None (0)'	System	13 Nov 2020 00:51:13
	System	13 Nov 2020 00:51:13

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:49', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9f584011-9b2c-49e1-92c2-d5c12abde1dc' User entered 'None (0)'	System	13 Nov 2020 00:51:13
	System	13 Nov 2020 00:51:13

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:55', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9f584011-9b2c-49e1-92c2-d5c12abde1dc' User entered 'None (0)'	System	13 Nov 2020 00:51:13
	System	13 Nov 2020 00:51:13



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:50:58', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9f584011-9b2c-49e1-92c2-d5c12abde1dc' User entered 'None (0)'	System	13 Nov 2020 00:51:13
	System	13 Nov 2020 00:51:13

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:51:04', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9f584011-9b2c-49e1-92c2-d5c12abde1dc' User entered 'None (0)'	System	13 Nov 2020 00:51:13
	System	13 Nov 2020 00:51:13

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:51:06', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9f584011-9b2c-49e1-92c2-d5c12abde1dc' User entered 'None (0)'	System	13 Nov 2020 00:51:13
	System	13 Nov 2020 00:51:13

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:51:08', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9f584011-9b2c-49e1-92c2-d5c12abde1dc' User entered 'No (N)'	System	13 Nov 2020 00:51:13
	System	13 Nov 2020 00:51:13

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-12T19:51:10', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9f584011-9b2c-49e1-92c2-d5c12abde1dc' User entered '12 Nov 2020 19:51'	System	13 Nov 2020 00:51:13
	System	13 Nov 2020 00:51:13

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '12 Nov 2020 18:25'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 2'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42

US3602154

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:14:33

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 03:18:42

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 3'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:37', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9159af4c-0242-455d-9016-fe81bc83b626' User entered 'None (0)'	System	14 Nov 2020 17:00:50
	System	14 Nov 2020 17:00:50

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:38', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9159af4c-0242-455d-9016-fe81bc83b626' User entered 'None (0)'	System	14 Nov 2020 17:00:50
	System	14 Nov 2020 17:00:50

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:40', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9159af4c-0242-455d-9016-fe81bc83b626' User entered 'None (0)'	System	14 Nov 2020 17:00:50
	System	14 Nov 2020 17:00:50

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:41', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9159af4c-0242-455d-9016-fe81bc83b626' User entered 'None (0)'	System	14 Nov 2020 17:00:50
	System	14 Nov 2020 17:00:50

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:42', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9159af4c-0242-455d-9016-fe81bc83b626' User entered 'None (0)'	System	14 Nov 2020 17:00:50
	System	14 Nov 2020 17:00:50



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:43', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9159af4c-0242-455d-9016-fe81bc83b626' User entered 'None (0)'	System	14 Nov 2020 17:00:50
	System	14 Nov 2020 17:00:50

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:45', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9159af4c-0242-455d-9016-fe81bc83b626' User entered 'No (N)'	System	14 Nov 2020 17:00:50
	System	14 Nov 2020 17:00:50

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-14T12:00:47', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '9159af4c-0242-455d-9016-fe81bc83b626' User entered '14 Nov 2020 12:00'	System	14 Nov 2020 17:00:50
	System	14 Nov 2020 17:00:50

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 4'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:37', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6168c1c2-9581-4aa8-ad02-59cb7b1c41cb' User entered 'None (0)'	System	15 Nov 2020 17:47:53
	System	15 Nov 2020 17:47:53

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:39', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6168c1c2-9581-4aa8-ad02-59cb7b1c41cb' User entered 'None (0)'	System	15 Nov 2020 17:47:53
	System	15 Nov 2020 17:47:53



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:40', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6168c1c2-9581-4aa8-ad02-59cb7b1c41cb' User entered 'None (0)'	System	15 Nov 2020 17:47:53
	System	15 Nov 2020 17:47:53

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:42', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6168c1c2-9581-4aa8-ad02-59cb7b1c41cb' User entered 'None (0)'	System	15 Nov 2020 17:47:53
	System	15 Nov 2020 17:47:53

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:43', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6168c1c2-9581-4aa8-ad02-59cb7b1c41cb' User entered 'None (0)'	System	15 Nov 2020 17:47:53
	System	15 Nov 2020 17:47:53

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:44', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6168c1c2-9581-4aa8-ad02-59cb7b1c41cb' User entered 'None (0)'	System	15 Nov 2020 17:47:53
	System	15 Nov 2020 17:47:53

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:46', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6168c1c2-9581-4aa8-ad02-59cb7b1c41cb' User entered 'No (N)'	System	15 Nov 2020 17:47:53
	System	15 Nov 2020 17:47:53

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-15T12:47:49', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6168c1c2-9581-4aa8-ad02-59cb7b1c41cb' User entered '15 Nov 2020 12:47'	System	15 Nov 2020 17:47:53
	System	15 Nov 2020 17:47:53

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 5'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:17', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '06d58b7c-6fae-4aab-bfe3-43bdcd4d16e3' User entered 'None (0)'	System	16 Nov 2020 17:27:33
	System	16 Nov 2020 17:27:33

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:18', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '06d58b7c-6fae-4aab-bfe3-43bdcd4d16e3' User entered 'None (0)'	System	16 Nov 2020 17:27:33
	System	16 Nov 2020 17:27:33

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:20', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '06d58b7c-6fae-4aab-bfe3-43bdcd4d16e3' User entered 'None (0)'	System	16 Nov 2020 17:27:33
	System	16 Nov 2020 17:27:33

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:21', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '06d58b7c-6fae-4aab-bfe3-43bdcd4d16e3' User entered 'None (0)'	System	16 Nov 2020 17:27:33
	System	16 Nov 2020 17:27:33

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:22', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '06d58b7c-6fae-4aab-bfe3-43bdcd4d16e3' User entered 'None (0)'	System	16 Nov 2020 17:27:33
	System	16 Nov 2020 17:27:33

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:24', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '06d58b7c-6fae-4aab-bfe3-43bdcd4d16e3' User entered 'None (0)'	System	16 Nov 2020 17:27:33
	System	16 Nov 2020 17:27:33

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:28', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '06d58b7c-6fae-4aab-bfe3-43bdcd4d16e3' User entered 'No (N)'	System	16 Nov 2020 17:27:33
	System	16 Nov 2020 17:27:33



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-16T12:27:30', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '06d58b7c-6fae-4aab-bfe3-43bdcd4d16e3' User entered '16 Nov 2020 12:27'	System	16 Nov 2020 17:27:33
	System	16 Nov 2020 17:27:33

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 6'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:53', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f89c0954-e62b-45ec-bcd3-18abd2045410' User entered 'None (0)'	System	17 Nov 2020 17:37:07
	System	17 Nov 2020 17:37:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:55', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f89c0954-e62b-45ec-bcd3-18abd2045410' User entered 'None (0)'	System	17 Nov 2020 17:37:07
	System	17 Nov 2020 17:37:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:56', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f89c0954-e62b-45ec-bcd3-18abd2045410' User entered 'None (0)'	System	17 Nov 2020 17:37:07
	System	17 Nov 2020 17:37:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:58', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f89c0954-e62b-45ec-bcd3-18abd2045410' User entered 'None (0)'	System	17 Nov 2020 17:37:07
	System	17 Nov 2020 17:37:07



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:36:59', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f89c0954-e62b-45ec-bcd3-18abd2045410' User entered 'None (0)'	System	17 Nov 2020 17:37:07
	System	17 Nov 2020 17:37:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:37:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f89c0954-e62b-45ec-bcd3-18abd2045410' User entered 'None (0)'	System	17 Nov 2020 17:37:07
	System	17 Nov 2020 17:37:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:37:02', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f89c0954-e62b-45ec-bcd3-18abd2045410' User entered 'No (N)'	System	17 Nov 2020 17:37:07
	System	17 Nov 2020 17:37:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-17T12:37:04', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'f89c0954-e62b-45ec-bcd3-18abd2045410' User entered '17 Nov 2020 12:37'	System	17 Nov 2020 17:37:07
	System	17 Nov 2020 17:37:07

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
Data entry locked.	System	12 Nov 2020 19:50:11
User entered 'Day 7'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:30', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8346a6f1-96d8-4bdf-a420-04bc96e44ed1' User entered 'None (0)'	System	18 Nov 2020 17:43:47
	System	18 Nov 2020 17:43:47



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:32', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8346a6f1-96d8-4bdf-a420-04bc96e44ed1' User entered 'None (0)'	System	18 Nov 2020 17:43:47
	System	18 Nov 2020 17:43:47

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:33', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8346a6f1-96d8-4bdf-a420-04bc96e44ed1' User entered 'None (0)'	System	18 Nov 2020 17:43:47
	System	18 Nov 2020 17:43:47

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:35', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8346a6f1-96d8-4bdf-a420-04bc96e44ed1' User entered 'None (0)'	System	18 Nov 2020 17:43:47
	System	18 Nov 2020 17:43:47

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:36', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8346a6f1-96d8-4bdf-a420-04bc96e44ed1' User entered 'None (0)'	System	18 Nov 2020 17:43:47
	System	18 Nov 2020 17:43:47

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:38', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8346a6f1-96d8-4bdf-a420-04bc96e44ed1' User entered 'None (0)'	System	18 Nov 2020 17:43:47
	System	18 Nov 2020 17:43:47

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

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 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:40', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8346a6f1-96d8-4bdf-a420-04bc96e44ed1' User entered 'No (N)'	System	18 Nov 2020 17:43:47
	System	18 Nov 2020 17:43:47

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-11-18T12:43:43', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '8346a6f1-96d8-4bdf-a420-04bc96e44ed1' User entered '18 Nov 2020 12:43'	System	18 Nov 2020 17:43:47
	System	18 Nov 2020 17:43:47

**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 19:50:11



**US3602154**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:14:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 03:18:42
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 19:50:11

**US3602154**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:17:24

**US3602154**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:17:24

**US3602154**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:17:24

**US3602154**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:17:24

**US3602154**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:17:33

**US3602154**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'I'	System	04 Dec 2020 23:17:33

**US3602154**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:18:20



**US3602154**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:18:20

**US3602154**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:18:20

**US3602154**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:18:20

**US3602154**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:18:26

**US3602154**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'I'	System	04 Dec 2020 23:18:26

**US3602154**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 10DEC2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 16:01:58
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 10DEC2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' answered with 'will update with visit notes' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 17:38:21
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 10DEC2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 17:22:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 23:18:53

**US3602154**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '3 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:18:53

**US3602154**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:18:53



**US3602154**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:18:53

**US3602154**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:19:00

**US3602154**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'I'	System	04 Dec 2020 23:19:00

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:38:30

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:38:30

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:38:30

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'VISIT3'	System	15 Dec 2020 17:38:30

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02



**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '13:40'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '10 Dec 2020 13:40'	System	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '80'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'bpm'	System	15 Dec 2020 17:39:02



**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'breaths/min'	System	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '113'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '67'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'mmHg'	System	15 Dec 2020 17:39:02

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29



**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:10

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:10

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:22

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:22

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '14:05'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:39:22

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '10 Dec 2020 14:05'	System	15 Dec 2020 17:39:22

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:37:47

**US3602154**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered '1'	System	15 Dec 2020 17:37:47



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-12-12T00:01:44', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29edfb1d-d2c9-45df-957f-5d5705b95346'	System	12 Dec 2020 05:02:29
User entered 'No (N)'	System	12 Dec 2020 05:02:29

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-12-12T00:01:49', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29edfb1d-d2c9-45df-957f-5d5705b95346'	System	12 Dec 2020 05:02:29
User entered 'No (N)'	System	12 Dec 2020 05:02:29

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-12-12T00:02:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29edfb1d-d2c9-45df-957f-5d5705b95346' User entered '12 Dec 2020 00:02:00'	System	12 Dec 2020 05:02:29
	System	12 Dec 2020 05:02:29

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-12-23T12:43:22', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6828aed-4e16-4981-9be1-6311a19cac59' User entered 'No (N)'	System	23 Dec 2020 17:43:30
	System	23 Dec 2020 17:43:30



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Have you been exposed to someone with 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 (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-12-23T12:43:24', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6828aed-4e16-4981-9be1-6311a19cac59' User entered 'No (N)'	System	23 Dec 2020 17:43:30
	System	23 Dec 2020 17:43:30

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-12-23T12:43:27', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'e6828aed-4e16-4981-9be1-6311a19cac59' User entered '23 Dec 2020 12:43:27'	System	23 Dec 2020 17:43:30
	System	23 Dec 2020 17:43:30

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-12-27T08:48:48', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '4e740a64-b1d9-49b8-ac60-3fab7ddf8a4'	System	27 Dec 2020 13:49:03
User entered 'No (N)'	System	27 Dec 2020 13:49:03

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-12-27T08:48:55', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '4e740a64-b1d9-49b8-ac60-3fab7ddf8a4'	System	27 Dec 2020 13:49:03
User entered 'No (N)'	System	27 Dec 2020 13:49:03

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (47F7A5F0-AA71-4FFA-A0F7-6E136109D272)', Time: '2020-12-27T08:49:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '4e740a64-b1d9-49b8-ac60-3fab7ddf8a4'	System	27 Dec 2020 13:49:03
User entered '27 Dec 2020 08:49:00'	System	27 Dec 2020 13:49:03



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-01-18T12:05:15', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6b29ba13-3faf-4b8e-baae-1d837094c6ed' User entered 'No (N)'	System	18 Jan 2021 17:05:38
	System	18 Jan 2021 17:05:38

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-01-18T12:05:18', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6b29ba13-3faf-4b8e-baae-1d837094c6ed' User entered 'No (N)'	System	18 Jan 2021 17:05:38

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-01-18T12:05:26', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '6b29ba13-3faf-4b8e-baae-1d837094c6ed' User entered '18 Jan 2021 12:05:26'	System	18 Jan 2021 17:05:38
	System	18 Jan 2021 17:05:38

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-01-23T00:13:41', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2a1b49e5-175d-44a5-9443-3e038a44580e' User entered 'No (N)'	System	23 Jan 2021 05:14:06
	System	23 Jan 2021 05:14:06



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-01-23T00:13:50', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2a1b49e5-175d-44a5-9443-3e038a44580e'	System	23 Jan 2021 05:14:06
User entered 'No (N)'	System	23 Jan 2021 05:14:06

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-01-23T00:14:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2a1b49e5-175d-44a5-9443-3e038a44580e' User entered '23 Jan 2021 00:14:00'	System	23 Jan 2021 05:14:06
	System	23 Jan 2021 05:14:06

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-01T12:00:29', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '765f3b50-ffcf-46a8-820b-32024b0f999b' User entered 'No (N)'	System	06 Feb 2021 05:14:03
	System	06 Feb 2021 05:14:03

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-01T12:00:32', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '765f3b50-ffcf-46a8-820b-32024b0f999b'	System	06 Feb 2021 05:14:03
User entered 'No (N)'	System	06 Feb 2021 05:14:03

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-01T12:00:35', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '765f3b50-ffcf-46a8-820b-32024b0f999b' User entered '01 Feb 2021 12:00:35'	System	06 Feb 2021 05:14:03
	System	06 Feb 2021 05:14:03



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-06T00:14:08', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd693bcae-c511-4a40-bdd8-3ae922031e23'	System	10 Feb 2021 15:06:52
User entered 'No (N)'	System	10 Feb 2021 15:06:52

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-06T00:14:12', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd693bcae-c511-4a40-bdd8-3ae922031e23'	System	10 Feb 2021 15:06:52
User entered 'No (N)'	System	10 Feb 2021 15:06:52

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-06T00:14:17', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'd693bcae-c511-4a40-bdd8-3ae922031e23'	System	10 Feb 2021 15:06:52
User entered '06 Feb 2021 00:14:17'	System	10 Feb 2021 15:06:52

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-13T00:30:59', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b671cdd0-f5fa-4ea3-8df4-9664d9f8c32a' User entered 'No (N)'	System	17 Feb 2021 17:30:53
	System	17 Feb 2021 17:30:53

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-13T00:31:03', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b671cdd0-f5fa-4ea3-8df4-9664d9f8c32a' User entered 'No (N)'	System	17 Feb 2021 17:30:53
	System	17 Feb 2021 17:30:53

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-13T00:31:05', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b671cdd0-f5fa-4ea3-8df4-9664d9f8c32a'	System	17 Feb 2021 17:30:53
User entered '13 Feb 2021 00:31:05'	System	17 Feb 2021 17:30:53

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-22T12:00:19', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '4f5775f2-45c9-4db6-a224-eeb68a810150'	System	22 Feb 2021 17:01:39
User entered 'No (N)'	System	22 Feb 2021 17:01:39



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-22T12:00:22', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '4f5775f2-45c9-4db6-a224-eeb68a810150'	System	22 Feb 2021 17:01:39
User entered 'No (N)'	System	22 Feb 2021 17:01:39

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-22T12:00:26', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '4f5775f2-45c9-4db6-a224-eeb68a810150'	System	22 Feb 2021 17:01:39
User entered '22 Feb 2021 12:00:26'	System	22 Feb 2021 17:01:39

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-27T10:27:44-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4e5d694-1496-46ef-ab1d-41f902c9881a' User entered 'No (N)'	System	27 Feb 2021 15:27:52
	System	27 Feb 2021 15:27:52

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-27T10:27:47-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4e5d694-1496-46ef-ab1d-41f902c9881a' User entered 'No (N)'	System	27 Feb 2021 15:27:52
	System	27 Feb 2021 15:27:52

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-27T10:27:49-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4e5d694-1496-46ef-ab1d-41f902c9881a' User entered '27 Feb 2021 15:27:49'	System	27 Feb 2021 15:27:52
	System	27 Feb 2021 15:27:52



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-06T00:02:32-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4fb3844-6f43-4b83-8a59-d36d46f8f7cd'	System	06 Mar 2021 05:05:25
User entered 'Yes (Y)'	System	06 Mar 2021 05:05:25

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-06T00:02:38-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4fb3844-6f43-4b83-8a59-d36d46f8f7cd'	System	06 Mar 2021 05:05:25
User entered 'No (N)'	System	06 Mar 2021 05:05:25

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-06T00:02:44-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4fb3844-6f43-4b83-8a59-d36d46f8f7cd'	System	06 Mar 2021 05:05:25
User entered 'No (N)'	System	06 Mar 2021 05:05:25

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-06T00:02:57-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4fb3844-6f43-4b83-8a59-d36d46f8f7cd'	System	06 Mar 2021 05:05:25
User entered 'No (N)'	System	06 Mar 2021 05:05:25

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-06T00:03:02-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: 'b4fb3844-6f43-4b83-8a59-d36d46f8f7cd'	System	06 Mar 2021 05:05:25
User entered '06 Mar 2021 00:03:02'	System	06 Mar 2021 05:05:25



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-15T11:47:34-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29b7bf93-601e-45a5-a2a4-0b6e7eff3989'	System	15 Mar 2021 15:47:43
User entered 'No (N)'	System	15 Mar 2021 15:47:43

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-15T11:47:36-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29b7bf93-601e-45a5-a2a4-0b6e7eff3989'	System	15 Mar 2021 15:47:43
User entered 'No (N)'	System	15 Mar 2021 15:47:43

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-15T11:47:40-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '29b7bf93-601e-45a5-a2a4-0b6e7eff3989' User entered '15 Mar 2021 11:47:40'	System	15 Mar 2021 15:47:43
	System	15 Mar 2021 15:47:43

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-22T12:01:01-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '90565549-3c8b-4311-b371-cff2be6c2d08'	System	22 Mar 2021 16:03:53
User entered 'No (N)'	System	22 Mar 2021 16:03:53

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-22T12:01:11-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '90565549-3c8b-4311-b371-cff2be6c2d08'	System	22 Mar 2021 16:03:53
User entered 'No (N)'	System	22 Mar 2021 16:03:53

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-22T12:01:17-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '90565549-3c8b-4311-b371-cff2be6c2d08'	System	22 Mar 2021 16:03:53
User entered '22 Mar 2021 12:01:17'	System	22 Mar 2021 16:03:53

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-29T12:24:28-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '59cf4b19-1eef-4ba8-97af-bd0c246b26f1' User entered 'No (N)'	System	29 Mar 2021 16:24:37
	System	29 Mar 2021 16:24:37



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-29T12:24:30-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '59cf4b19-1eef-4ba8-97af-bd0c246b26f1'	System	29 Mar 2021 16:24:37
User entered 'No (N)'	System	29 Mar 2021 16:24:37

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-03-29T12:24:33-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '59cf4b19-1eef-4ba8-97af-bd0c246b26f1' User entered '29 Mar 2021 12:24:33'	System	29 Mar 2021 16:24:37
	System	29 Mar 2021 16:24:37

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-07T08:02:40-07:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3a110241-9007-4ed3-8626-e96761dfbccf' User entered 'No (N)'	System	07 Apr 2021 15:02:49

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-07T08:02:43-07:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3a110241-9007-4ed3-8626-e96761dfbccf' User entered 'No (N)'	System	07 Apr 2021 15:02:49

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-07T08:02:45-07:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '3a110241-9007-4ed3-8626-e96761dfbccf' User entered '07 Apr 2021 08:02:45'	System	07 Apr 2021 15:02:49
	System	07 Apr 2021 15:02:49



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-10T10:15:12-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2fb5803b-e73e-405a-b836-9ca0cde5d8b0'	System	10 Apr 2021 14:15:20
User entered 'No (N)'	System	10 Apr 2021 14:15:20

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-10T10:15:15-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2fb5803b-e73e-405a-b836-9ca0cde5d8b0'	System	10 Apr 2021 14:15:20
User entered 'No (N)'	System	10 Apr 2021 14:15:20

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-10T10:15:17-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '2fb5803b-e73e-405a-b836-9ca0cde5d8b0'	System	10 Apr 2021 14:15:20
User entered '10 Apr 2021 10:15:17'	System	10 Apr 2021 14:15:20

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-19T17:27:15-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0ca61a78-5df3-4ff7-b8c1-4254d132d390'	System	19 Apr 2021 21:27:25
User entered 'No (N)'	System	19 Apr 2021 21:27:25

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-19T17:27:16-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0ca61a78-5df3-4ff7-b8c1-4254d132d390'	System	19 Apr 2021 21:27:25
User entered 'No (N)'	System	19 Apr 2021 21:27:25

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-19T17:27:20-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0ca61a78-5df3-4ff7-b8c1-4254d132d390'	System	19 Apr 2021 21:27:25
User entered '19 Apr 2021 17:27:20'	System	19 Apr 2021 21:27:25

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-28T00:02:36-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0798dd3c-b1d3-48cf-a474-afc6ef746208'	System	29 Apr 2021 04:59:47
User entered 'No (N)'	System	29 Apr 2021 04:59:47



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-28T00:02:40-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0798dd3c-b1d3-48cf-a474-afc6ef746208' User entered 'No (N)'	System	29 Apr 2021 04:59:47

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-04-28T00:02:44-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0798dd3c-b1d3-48cf-a474-afc6ef746208' User entered '28 Apr 2021 00:02:44'	System	29 Apr 2021 04:59:47
	System	29 Apr 2021 04:59:47

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-05-01T01:40:42-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '4060b93a-d6b9-4679-b4a8-3d9248231ca3'	System	01 May 2021 05:42:15
User entered 'No (N)'	System	01 May 2021 05:42:15

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

Have you been exposed to someone with 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 (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-05-01T01:40:48-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '4060b93a-d6b9-4679-b4a8-3d9248231ca3'	System	01 May 2021 05:42:15
User entered 'No (N)'	System	01 May 2021 05:42:15

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-05-01T01:40:52-04:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '4060b93a-d6b9-4679-b4a8-3d9248231ca3'	System	01 May 2021 05:42:15
User entered '01 May 2021 01:40:52'	System	01 May 2021 05:42:15



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '10 Dec 2022 00:01'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '14 Dec 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '17 Dec 2022 00:01'	System	20 Nov 2020 12:48:16



**US3602154**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:14:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:16
Amendment Manager: User entered '21 Dec 2022 23:59'	System	20 Nov 2020 12:48:16

**US3602154**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:14:33**

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 15:18:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-27T10:27:58-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0b35c040-4087-4e7e-8ce9-01301e973e2e'	System	27 Feb 2021 15:28:07
User entered 'No (N)'	System	27 Feb 2021 15:28:07

**US3602154**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:18:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7753EE6C-CD76-44A6-8DEA-77666ACB50BA)', Time: '2021-02-27T10:28:02-05:00', User OID: 'PatientReportedOutcome (US3602154)', ODM File OID: '0b35c040-4087-4e7e-8ce9-01301e973e2e' User entered '27 Feb 2021 15:28:02'	System	27 Feb 2021 15:28:07
	System	27 Feb 2021 15:28:07

**US3602154**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:18:20

**US3602154**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:18:20

**US3602154**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:18:20

**US3602154**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:18:20

**US3602154**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:18:33



**US3602154**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:36:29
User entered 'I'	System	27 Jan 2021 19:18:33

**US3602154**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:06:18
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 06:17:17

**US3602154**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:06:18
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 06:17:17

**US3602154**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:06:18
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 06:17:17

**US3602154**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Day 119 Feb 2, 2021 - Safety call overlaps with OL Day 1 visit which took place on 2/9/2021. As per protocol, no additional safety call was required.' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:06:18
User entered empty.	(b) (4), (b) (6)	03 Mar 2021 06:17:17

**US3602154**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 06:17:52

**US3602154**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User entered 'I'	System	03 Mar 2021 06:17:52

**US3602154**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:49



**US3602154**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:49

**US3602154**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:49

**US3602154**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Subject visited study site for OL Dose 2/D29 appointment on 9/March/2021. His scheduled day 149 SC--scheduled for 12/March/21 overlaps with this encounter. Will continue to follow appropriately.'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:07:49

**US3602154**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 21:08:00

**US3602154**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:12:06
User entered 'I'	System	23 Mar 2021 21:08:00

**US3602154**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:11

**US3602154**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:11

**US3602154**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:11



**US3602154**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Part B: OLD-57 visit is combined with Part A: Safety Call #179'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:11

**US3602154**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:19

**US3602154**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 17:56:19

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:41
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:58:40

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:14:33**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:41
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '22:04'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:58:40

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:14:33**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:41
User entered '7 Jan 2021 22:04'	System	09 Jan 2021 00:58:40

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:14:33**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:41
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Safety Call (Safety Call)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:58:40

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:14:33**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:41
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:58:40



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per CDM: Assessment Not Done is selected, yet data is present. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:26:10
Query 'Per CDM: Assessment Not Done is selected, yet data is present. Please review and reconcile. ' answered with 'Entry updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:07:12
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Mar 2021 16:06:31
User opened query 'Per CDM: Assessment Not Done is selected, yet data is present. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:17:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered '0'	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User entered '%'	System	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done; reason for	(b) (4)	
change New Information	(b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:01:11



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51
User entered empty.	(b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:01:11

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '7 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51



US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:14:33

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per CDM: Assessment Not Done is selected, yet data is present. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 08:26:15
Query 'Per CDM: Assessment Not Done is selected, yet data is present. Please review and reconcile. ' answered with 'Entry updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:09:24
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Mar 2021 16:08:56
User opened query 'Per CDM: Assessment Not Done is selected, yet data is present. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:17:43
User entered '1'	(b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User entered '%'	System	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Jan 2021 01:03:51

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '98'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User entered '%'	System	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	09 Jan 2021 01:07:01
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Jan 2021 01:06:30

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Jan 2021'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '93'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User entered '%'	System	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 06:47:05



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '98'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User entered '%'	System	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:04:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '99'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User entered '%'	System	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '96.9' F	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:30:55
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:10

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:14:33

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD has a sample date 08JAN2020 under Illness Visit Day1 which is missing in EDC and in EDC COVID swab dated 08Jan2021 is recorded. Please review Preclarus to verify the Year reported and update Preclarus, if applicable. Also confirm the correct date in the response and record the data in EDC.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 13:11:05
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD has a sample date 08JAN2020 under Illness Visit Day1 which is missing in EDC and in EDC COVID swab dated 08Jan2021 is recorded. Please review Preclarus to verify the Year reported and update Preclarus, if applicable. Also confirm the correct date in the response and record the data in EDC.	(b) (4), (b) (6)	13 Jan 2021 16:45:21
' answered with 'Updated.' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD has a sample date 08JAN2020 under Illness Visit Day1 which is missing in EDC and in EDC COVID swab dated 08Jan2021 is recorded. Please review Preclarus to verify the Year reported and update Preclarus, if applicable. Also confirm the correct date in the response and record the data in EDC.	(b) (4), (b) (6)	13 Jan 2021 07:13:05
' (Site from DM).		
User entered '8 Jan 2021'	(b) (4), (b) (6)	10 Jan 2021 07:08:20

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:14:33**

[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 14:31:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 07:08:20

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:14:33

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 14:31:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per CDM:Kindly update the response once data is received.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 03:22:05
Query 'Per CDM:Kindly update the response once data is received.Thank you.' answered with 'PCR is negative per source.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 16:43:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 16:43:18
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Jan 2021 04:19:47
User opened query 'Per CDM:Kindly update the response once data is received.Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 04:19:31
Query 'Data is required. Please complete.' answered with 'Data will be entered whet PCR results are received.' (Site from System).	(b) (4), (b) (6)	10 Jan 2021 07:09:30
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Jan 2021 07:08:20
User entered empty.	(b) (4), (b) (6)	10 Jan 2021 07:08:20

US3602154

Folder: Covid-19 Assessment 07 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:14:33

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "12-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "08-JAN-2021" for illness visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 05:35:27
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "12-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "08-JAN-2021" for illness visit. Kindly review the collection date and update as appropriate, else clarify. ' answered with 'Updated per query.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 22:04:32
User entered '8 Jan 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Feb 2021 22:04:19
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "12-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "08-JAN-2021" for illness visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 10:54:24
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Jan 2021 19:19:27
User entered '8 Jan 2021'	(b) (4), (b) (6)	10 Jan 2021 07:08:20



**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:14:33**

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	10 Jan 2021 07:08:20

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:14:33**

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Jan 2021 07:08:20

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:14:33**

[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 14:31:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Jan 2021 07:08:20

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:14:33**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Jan 2021 07:08:20

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:14:33**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:04
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Jan 2021 07:08:20

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:14:33**

**COVID-19 Positive (CSA Programming Field Only)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:04
User entered '0'	System	13 Jan 2021 16:43:18

**US3602154**

**Folder: Covid-19 Assessment 07 Jan 2021**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:10
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:27:07

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	27 Jan 2021 19:20:54



**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)' reason for change: New Information	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 15:41:59
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	17 Feb 2021 17:57:43
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	15 Feb 2021 22:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 19:20:54

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per GCL Lab Recon: Saliva: Response noted, however, per Preclarus report, there is no record of this subject ID US3602154 with Saliva sample collected on "10 JAN 2021" , please kindly review once again and confirm if the sample was collected or not, and if there is any SUBJECT ID entry error or ID mismatch, as there is no record of this subject ID per Preclarus report. Please also confirm if this accession number " 1F602584173" given in the response belongs to this subject ID, as there is no record of this Accession number as well in Preclarus report. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 06:49:18
User entered empty; reason for change New Information	(b) (4), (b) (6)	18 Feb 2021 15:41:59
User entered '10 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	17 Feb 2021 17:57:43
Query 'Per GCL Lab Recon: Saliva: Response noted, however, per Preclarus report, there is no record of this subject ID US3602154 with Saliva sample collected on "10 JAN 2021" , please kindly review once again and confirm if the sample was collected or not, and if there is any SUBJECT ID entry error or ID mismatch, as there is no record of this subject ID per Preclarus report. Please also confirm if this accession number " 1F602584173" given in the response belongs to this subject ID, as there is no record of this Accession number as well in Preclarus report. Thank you.' answered with 'Per source, research coordinator (b) (6) documented on 02/10/2021: "Day 3 saliva sample accidentally discarded by none study member. Discovered on 10Feb2021 by (b) (6)." Saliva collection not done. Pending re-confirmation from site manager (b) (6) (b) (6). Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 22:56:15
User entered empty; reason for change New Information	(b) (4), (b) (6)	15 Feb 2021 22:54:50

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: Saliva: Response noted, however, per Preclarus report, there is no record of this subject ID US3602154 with Saliva sample collected on "10 JAN 2021" , please kindly review once again and confirm if the sample was collected or not, and if there is any SUBJECT ID entry error or ID mismatch, as there is no record of this subject ID per Preclarus report. Please also confirm if this accession number " 1F602584173" given in the response belongs to this subject ID, as there is no record of this Accession number as well in Preclarus report. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Feb 2021 15:53:07
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10JAN2021 is recorded under Illness visit in EDC, however the same 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)	13 Feb 2021 15:49:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10JAN2021 is recorded under Illness visit in EDC, however the same 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 'Accession # : 1F602584173' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 21:20:30
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10JAN2021 is recorded under Illness visit in EDC, however the same 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)	09 Feb 2021 07:12:15
User entered '10 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 19:20:54

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05



**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	27 Jan 2021 19:21:05



**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:14:33**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:14:33**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:21:05

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:53:35

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:53:35

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[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 19:17:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:53:35



**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:02
User entered 'SICKD1'	System	09 Jan 2021 00:53:35

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '08:26'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User entered '8 Jan 2021 08:26'	System	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02
DataPoint set to visible.	System	09 Jan 2021 00:53:35

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02
DataPoint set to visible.	System	09 Jan 2021 00:53:35

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02



**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '80'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User entered 'bpm'	System	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '18'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User entered 'breaths/min'	System	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '115'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User entered 'mmHg'	System	09 Jan 2021 00:55:02



**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '71'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05
User entered 'mmHg'	System	09 Jan 2021 00:55:02

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:05

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:21

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:21

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:14:33**

[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 19:17:11
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:35

**US3602154**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:14:33**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 19:17:11
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 00:55:35



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:19:29

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:19:29

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[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 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:19:29

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 21:19:29

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[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 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:51:08

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
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 09:51:08



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '1'	System	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'I'	System	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered empty.	System	10 Feb 2021 21:25:55
DataPoint set to visible.	System	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered empty.	System	10 Feb 2021 21:25:55
DataPoint set to visible.	System	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '15:40'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '9 Feb 2021 15:40'	System	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '94'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'bpm'	System	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'breaths/min'	System	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '110'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mmHg'	System	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '67'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mmHg'	System	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:14:33**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered empty.	System	10 Feb 2021 21:25:55
DataPoint set to visible.	System	10 Feb 2021 21:21:35



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '16:35'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '9 Feb 2021 16:35'	System	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.4' F	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '84'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'bpm'	System	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '18'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'breaths/min'	System	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '114'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mmHg'	System	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '70'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:25:55

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mmHg'	System	10 Feb 2021 21:25:55



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:21:44

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:21:44

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:22:15

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:22:15

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:22:15

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mRNA-1273'	System	10 Feb 2021 21:22:15
DataPoint set to visible.	System	10 Feb 2021 21:21:35

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:22:15

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '16:05'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:22:15



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '9 Feb 2021 16:05'	System	10 Feb 2021 21:22:15

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:22:15

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'ONCE'	System	10 Feb 2021 21:22:15

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 21:22:15

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:22:47

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:22:47

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '14:40'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:22:47

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '9 Feb 2021 14:40'	System	10 Feb 2021 21:22:47



**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:23:01

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:14:33**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:23:01

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:14:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '14:44'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:23:01

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:14:33**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '9 Feb 2021 14:44'	System	10 Feb 2021 21:23:01

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 21:26:23

**US3602154**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'I'	System	10 Feb 2021 21:26:23

**US3602154**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:54:15

**US3602154**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:54:15



**US3602154**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:54:15

**US3602154**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:54:15

**US3602154**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:54:29

**US3602154**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'I'	System	17 Feb 2021 17:54:29

**US3602154**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '1'	System	17 Feb 2021 17:54:29
DataPoint set to visible.	System	17 Feb 2021 17:54:29

**US3602154**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:17:18

**US3602154**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 22:17:38
User entered '8 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 22:17:18

**US3602154**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[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 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:17:18



**US3602154**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'OLD29'	System	09 Mar 2021 22:17:18

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '14:10'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '9 Mar 2021 14:10'	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26



**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '63'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'bpm'	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'breaths/min'	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '104'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mmHg'	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '69'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26



**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mmHg'	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '16:50'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '9 Mar 2021 16:50'	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26



**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '59'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'bpm'	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '18'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'breaths/min'	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	25 Mar 2021 15:21:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).		25 Mar 2021 15:21:34
User entered '123' reason for change: New Information	(b) (4), (b) (6)	25 Mar 2021 15:21:34
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Mar 2021 18:49:26
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mmHg'	System	25 Mar 2021 15:21:34
User entered empty.	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	25 Mar 2021 15:21:34
Query 'Data is required. Please provide.' answered by System data change (Site from System).		25 Mar 2021 15:21:34
User entered '78' reason for change: New Information	(b) (4), (b) (6)	25 Mar 2021 15:21:34
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Mar 2021 18:49:26
User entered empty.	(b) (4), (b) (6)	12 Mar 2021 18:49:26



**US3602154**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mmHg'	System	25 Mar 2021 15:21:34
User entered empty.	System	12 Mar 2021 18:49:26

**US3602154**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:17:28

**US3602154**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	09 Mar 2021 22:17:38
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Mar 2021 22:17:28
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 22:17:28

**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:18:08

**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:18:08

**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

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 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:18:08

**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'mRNA-1273'	System	09 Mar 2021 22:18:08
DataPoint set to visible.	System	17 Feb 2021 17:54:29

**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '9 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:18:08



**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '16:20'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:18:08

**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered '9 Mar 2021 16:20'	System	09 Mar 2021 22:18:08

**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:18:08

**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'ONCE'	System	09 Mar 2021 22:18:08

**US3602154**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:14:33**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 22:18:08

**US3602154**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 19:06:12

**US3602154**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'I'	System	12 Mar 2021 19:06:12

**US3602154**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:22:05



**US3602154**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:22:05

**US3602154**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:22:05

**US3602154**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:14:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:22:05

**US3602154**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:22:14

**US3602154**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:14:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:07:54
User entered 'I'	System	30 Mar 2021 18:22:14

**US3602154**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:36

**US3602154**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:36

**US3602154**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:36



**US3602154**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:14:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	14 Apr 2021 17:56:36

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '13:40'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 13:40'	System	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Temporal/Forehead scanner was used'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18



**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '82'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '20'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '132'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '72'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:18

**US3602154**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:14:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	14 Apr 2021 17:59:18



**US3602154**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:44

**US3602154**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:14:33**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:56:44

**US3602154**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:57

**US3602154**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:57

**US3602154**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	15 Apr 2021 02:39:00
User entered '13:50'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:59:57

**US3602154**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:14:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 13:50'	System	14 Apr 2021 17:59:57

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:14:33**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:59:38
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:28:13
User signature succeeded.	Bindu Balani (b) (4)	19 Mar 2021 17:46:57
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 16:09:39
User entered 'No (N)'	(b) (4), (b) (6)	03 Mar 2021 03:36:27

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:00:16
User entered	System	08 Mar 2021 16:21:32
'USA-US079-2021-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	08 Mar 2021 16:21:32



US3602154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:03:04
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Subject was assessed for potential covid-19 infection. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:03:32
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 07:02:06
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Non-cardiac chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 14:21:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 14:21:53
Data point term sent to Coder	System	09 Mar 2021 22:29:30
Coding entries removed.	(b) (4), (b) (6)	09 Mar 2021 22:29:14
User entered 'Non - Cardiac CHEST PAIN' reason for change: New Information	(b) (4), (b) (6)	09 Mar 2021 22:29:14
Data point term sent to Coder	System	09 Mar 2021 18:18:00
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ? ' (Site from System).	System	09 Mar 2021 18:17:14

US3602154

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:33

[Adverse event](#)

Audit	User	Time (GMT)
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ? ' answered with 'UNKNOWN etiology per source.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 18:17:14
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ? ' (Site from System).	Coder Import (b) (4)	07 Mar 2021 16:06:14
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 16:15:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Mar 2021 16:15:53
Data point term sent to Coder	System	05 Mar 2021 16:14:40
User entered 'Chest Pain'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '26 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:13:50



**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '27 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 18:46:36
User entered '26 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	05 Mar 2021 16:14:20
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	05 Mar 2021 16:13:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:13:50



**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 14:00:32
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'Dates updated.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 18:46:50
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:54:36
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)	08 Mar 2021 04:38:41
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Updated.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 16:15:36
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		05 Mar 2021 16:14:20
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		05 Mar 2021 16:14:20
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	05 Mar 2021 16:14:20
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 16:14:20

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User entered '0'	System	05 Mar 2021 16:13:50
	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '26 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '27 Feb 2021'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Mar 2021 18:19:00
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:13:50



**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:16
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 09 Feb 2021, then event occurred).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:26:22
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 09 Feb 2021, then event occurred).' answered with 'Updated.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 01:22:40
User entered 'None (NONE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Mar 2021 01:22:21
DataPoint Un-verified.	(b) (4), (b) (6)	18 Mar 2021 13:55:22
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 09 Feb 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:54:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Mar 2021 16:13:50



**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	05 Mar 2021 16:13:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:26:17
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:55:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Med records sent 15Mar ' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 18:16:51
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 14:00:50
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'Subject's MH added already (prior to onset of study)' (Site from Safety).	(b) (4), (b) (6)	13 Mar 2021 16:45:28
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:54:56
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 16:54:46

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Pt had sudden onset of chest pain and went to the hospital and was given aspirin with resolution of the chest pain , workup after ( submitted ) did not reveal definitive cardiac issues and is rec to see a cardiologist in the next week . The differential was cardiac versus GERD on discharge.'	(b) (4), (b) (6)	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Mar 2021 16:13:50

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Mar 2021 18:19:00

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 22:17:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 22:17:41
Data point term sent to Coder	System	09 Mar 2021 22:16:19
User entered 'Upper Respiratory Tract Infection'	(b) (4), (b) (6)	09 Mar 2021 22:15:37



**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '6 Jan 2021'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User entered empty.	System	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '11 Jan 2021'	(b) (4), (b) (6)	09 Mar 2021 22:15:37



**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User entered empty.	System	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'No (N)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 22:15:37



**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37



**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:24:27
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per CDM: The adverse event started after the subject was dosed at V2D29 and before the OL-D1 visit. Please review if the action taken with investigational product should be updated to "Not applicable". Thank you. ' (Site from DM).	(b) (4)	
Query 'Per CDM: The adverse event started after the subject was dosed at V2D29 and before the OL-D1 visit. Please review if the action taken with investigational product should be updated to "Not applicable". Thank you. ' answered with 'Entry updated per query request. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 11:54:58
Query 'Per CDM: The adverse event started after the subject was dosed at V2D29 and before the OL-D1 visit. Please review if the action taken with investigational product should be updated to "Not applicable". Thank you. ' answered with 'Entry updated per query request. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 17:52:46
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 17:52:17
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Mar 2021 17:52:17
User opened query 'Per CDM: The adverse event started after the subject was dosed at V2D29 and before the OL-D1 visit. Please review if the action taken with investigational product should be updated to "Not applicable". Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 07:25:56
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'l'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered '0'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:55:03
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User entered '0'	System	09 Mar 2021 22:15:37



**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23
User entered 'I'	System	09 Mar 2021 22:15:37

**US3602154**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:23

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:14:33**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:59:38
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:54

US3602154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
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.	(b) (4) Coder Import (b) (4)	04 Nov 2020 02:53:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 02:53:06
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 05:05:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 05:05:22
Data point term sent to Coder	System	15 Oct 2020 21:37:38
User entered 'Vitamin D'	(b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:56:22
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'for dietary supplement'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '2000'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 21:36:42

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 21:36:42

US3602154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 09:22:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	16 Feb 2021 09:22:54
Data point term sent to Coder	System	12 Feb 2021 21:42:25
Coding entries removed.	(b) (4), (b) (6)	12 Feb 2021 21:42:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: DAYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 15:41:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	11 Jan 2021 15:41:01
Data point term sent to Coder	System	11 Jan 2021 03:07:33
User entered 'DayQuil Cold and Flu (Acetaminophen 325 mg; Dextromethorphan HBr 10 mg; Phenylephrine HCl 5 mg)'	(b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

US3602154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per DM CLR;Requery:Response noted,however no AE has been updated for the corresponding CM in AE eCRF.Kindly review and update accordingly.Thank you.' (Site from DM). Query 'Per DM CLR;Requery:Response noted,however no AE has been updated for the corresponding CM in AE eCRF.Kindly review and update accordingly.Thank you.' answered with 'Symptoms in symptom log/tracker in the covid-19 assessment folder.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 10:08:43
Query 'Per DM CLR;Requery:Response noted,however no AE has been updated for the corresponding CM in AE eCRF.Kindly review and update accordingly.Thank you.' answered with 'Symptoms in symptom log/tracker in the covid-19 assessment folder.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 19:55:44
User opened query 'Per DM CLR;Requery:Response noted,however no AE has been updated for the corresponding CM in AE eCRF.Kindly review and update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 08:42:36
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. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 08:40:20
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. ' answered with 'Updated indication.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 21:42:09
User entered 'COUGH, NASAL CONGESTION, AND RUNNY NOSE - captured in symptom tracker' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Feb 2021 21:42:05
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. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:24:19
User entered 'Cough, nasal congestion, and runny nose'	(b) (4), (b) (6)	11 Jan 2021 03:06:53



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '325/10/5'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User entered empty.	System	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User entered empty.	System	11 Jan 2021 03:06:53

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:02
User entered empty.	System	11 Jan 2021 03:06:53

US3602154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: ROBITUSSIN COUGH+CHEST CONGESTION DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:02:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 11:02:49
Data point term sent to Coder	System	27 Jan 2021 19:30:52
User entered 'ROBITUSSIN Cough+Chest Congestion DM (Dextromethorphan HBr, 20MG, Guaifenesin 200mg per 20ML)'	(b) (4), (b) (6)	27 Jan 2021 19:29:59



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or 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. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:57:59
Query 'Per DM CLR: Please note there is no ongoing MH condition or 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. ' answered with 'CAPTURED IN SYMPTOM LOG TRACKER' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 22:49:20
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or 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. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:18:21
User entered 'Cough - captured in symptom log tracker'	(b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '20'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '8 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User entered empty.	System	27 Jan 2021 19:29:59

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User entered empty.	System	27 Jan 2021 19:29:59



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:05
User entered empty.	System	27 Jan 2021 19:29:59

US3602154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:33:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:33:27
Data point term sent to Coder	System	27 Jan 2021 19:32:54
User entered 'NyQuil Cold and Flu (acetaminophen 325 mg; Dextromethorphan HBr 15 mg; Doxylamine Succinate 6.25 mg)'	(b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or 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. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:58:09
Query 'Per DM CLR: Please note there is no ongoing MH condition or 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. ' answered with 'CAPTURED IN SYMPTOM LOG TRACKER' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 22:49:33
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or 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. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 17:18:32
User entered 'Sinus/Nasal Congestion - captured in symptom log tracker'	(b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'capsule (CAPSULE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:32:03



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User entered empty.	System	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User entered empty.	System	27 Jan 2021 19:32:03

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:39:08
User entered empty.	System	27 Jan 2021 19:32:03

US3602154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
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)	09 Mar 2021 22:28:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 22:28:40
Data point term sent to Coder	System	09 Mar 2021 22:27:28
User entered 'Aspirin'	(b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Cardiac prevention'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '81'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '27 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 22:26:39

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 22:26:39

US3602154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
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: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Mar 2021 22:29:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 22:29:50
Data point term sent to Coder	System	09 Mar 2021 22:28:29
User entered 'Protonix'	(b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

US3602154

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:33

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 03:23:51
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'When subject had the MAAE 'Non-cardiac Chest pain', the narrative states "Pt had a sudden onset of chest pain and went to the hospital and was given aspirin with resolution of the chest pain, workup after (submitted) did not reveal definitive cardiac issues and is rec to a cardiologist in the next week. The differential was cardiac versus GERD on discharge", so that is why subject was prescribed con meds "protonix - for GERD". Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:24:48
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 09:19:29
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'GERD'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '40'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '27 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08



**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:14:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 22:28:08

**US3602154**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:14:33**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:34:45



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'USA-US079-2021-MRNA-1273-P301000005'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Bindu'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Balani'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'NJ'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:48:06
User entered 'US'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Mar 2021 15:38:18
User entered '4'	System	23 Mar 2021 13:46:46
User entered '3'	System	15 Mar 2021 14:01:35
User entered '2'	System	10 Mar 2021 14:48:24
User entered '1'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'USA-US079-2021-MRNA-1273-P301000005'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Bindu'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Balani'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'NJ'	System	08 Mar 2021 16:21:32



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:48:06
User entered 'US'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Mar 2021 15:38:18
User entered '4'	System	23 Mar 2021 13:46:46
User entered '3'	System	15 Mar 2021 14:01:35
User entered '2'	System	10 Mar 2021 14:48:24
User entered '1'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
User entered '08/Mar/2021 10:23'	System	08 Mar 2021 16:23:26

US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:14:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:48:06
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'USA-US079-2021-MRNA-1273-P301000005'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Bindu'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Balani'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'NJ'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:48:06
User entered 'US'	System	08 Mar 2021 16:23:26



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Mar 2021 15:38:18
User entered '4'	System	23 Mar 2021 13:46:46
User entered '3'	System	15 Mar 2021 14:01:35
User entered '2'	System	10 Mar 2021 14:48:24
User entered '1'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
User entered '10/Mar/2021 08:48'	System	10 Mar 2021 14:48:24

US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:14:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 14:48:24

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'USA-US079-2021-MRNA-1273-P301000005'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Bindu'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Balani'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'NJ'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:48:06
User entered 'US'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Mar 2021 15:38:18
User entered '4'	System	23 Mar 2021 13:46:46
User entered '3'	System	15 Mar 2021 14:01:35
User entered '2'	System	10 Mar 2021 14:48:24
User entered '1'	System	08 Mar 2021 16:23:26



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
User entered '15/Mar/2021 10:01'	System	15 Mar 2021 14:01:35

US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:14:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 14:01:35

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'USA-US079-2021-MRNA-1273-P301000005'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Bindu'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Balani'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'NJ'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:48:06
User entered 'US'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Mar 2021 15:38:18
User entered '4'	System	23 Mar 2021 13:46:46
User entered '3'	System	15 Mar 2021 14:01:35
User entered '2'	System	10 Mar 2021 14:48:24
User entered '1'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:08
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '23/Mar/2021 06:46'	(b) (4) System	23 Mar 2021 13:46:46



US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:14:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:09
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 13:46:46

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'USA-US079-2021-MRNA-1273-P301000005'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Yes (Y)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32



**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'No (N)'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Bindu'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'Balani'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 16:23:17
User entered 'NJ'	System	08 Mar 2021 16:21:32

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 13:56:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:48:06
User entered 'US'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:14:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Mar 2021 15:38:18
User entered '4'	System	23 Mar 2021 13:46:46
User entered '3'	System	15 Mar 2021 14:01:35
User entered '2'	System	10 Mar 2021 14:48:24
User entered '1'	System	08 Mar 2021 16:23:26

**US3602154**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:14:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:15
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered '23/Mar/2021 11:38'	(b) (4) System	23 Mar 2021 15:38:18

US3602154

Folder: SAE USA-US079-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:14:33

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:25:17
User signature succeeded.	Bindu Balani (b) (4)	05 Apr 2021 21:52:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:38:18