

US3152162 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:27:55

All time stamps listed in this document are displayed in GMT

US3152162

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

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Participant ID

US3152162

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

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US3152162

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Date of Informed Consent ( <i>dd MMM yyyy</i> )	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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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) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Condition	UTERINE LEIOMYOMA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2001
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Condition	HERPES LABIALIS
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:20
Height (xxx.x)	160.7 cm
Weight (xxx.x)	95.5 kg
BMI (xxx.x)	36.98040 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 17 Feb 2021 04:10:57

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Date of assessment (dd MMM yyyy) 13 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2018

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 04:10:57

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Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 13 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 04:10:57

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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**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 04:10:57

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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)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:10:57

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

Visit date (dd MMM yyyy)	13 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103810

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) 17 Feb 2021 04:10:57

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Height	ND - Not Done
Weight	ND - Not Done



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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)	13 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:20
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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)	13 AUG 2020
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:34
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 13:02 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 13:02

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) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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

Collection date (dd MMM yyyy)	13 AUG 2020
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Collection time (00:00-23:59)	11:49 (24 HR)
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Collection date and time (derived)	13 AUG 2020 11:49
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:11	13 AUG 2020 12:11
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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: 09 Jun 2021 15:27:55

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 13:38

PC Open Date & Time

13 AUG 2020 13:22

PC Close Date & Time

13 AUG 2020 15:52

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	13 AUG 2020 19:54
PC Open Date & Time	13 AUG 2020 16:47
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

14 AUG 2020 12:51

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**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

98.6 °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 AUG 2020 20:56

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**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

98.6 °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

16 AUG 2020 14:45

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 18:06

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 11:00

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 11:19

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59



US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**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

13 AUG 2020 13:39

PC Open Date & Time

13 AUG 2020 13:22

PC Close Date & Time

13 AUG 2020 15:52

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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

1

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 19:58

PC Open Date & Time

13 AUG 2020 16:47

PC Close Date & Time

14 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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

3

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

14 AUG 2020 12:53

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**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

15 AUG 2020 21:02

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**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

16 AUG 2020 14:46

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**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

17 AUG 2020 18:07

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**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

19 AUG 2020 11:01

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**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

20 AUG 2020 11:19

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**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 ☐

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 13:39
PC Open Date & Time	13 AUG 2020 13:22
PC Close Date & Time	13 AUG 2020 15:52

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**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 ☐

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 19:59
PC Open Date & Time	13 AUG 2020 16:47
PC Close Date & Time	14 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**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 ☒

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 12:55
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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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US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:05
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 14:47
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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 ☒

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 18:07
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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 ☒

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 11:01
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**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 ☒

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EAB) (1725)

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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



US3152162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3152162

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3152162

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3152162

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3152162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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)	10 SEP 2020
Time of assessment (00:00-23:59)	15:25 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:25
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG



US3152162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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)	10 SEP 2020
Time of assessment (00:00-23:59)	17:03 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 17:03
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3152162

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3152162

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3152162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 16:33 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 16:33

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

US3152162

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	15:37 (24 HR)
Collection date and time (derived)	10 SEP 2020 15:37

US3152162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:50	10 SEP 2020 15:50
Nasopharyngeal Swab 2	No		

US3152162

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 17:06

PC Open Date & Time

10 SEP 2020 16:53

PC Close Date & Time

10 SEP 2020 19:23



US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	11 SEP 2020 10:10
PC Open Date & Time	10 SEP 2020 20:18
PC Close Date & Time	11 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:56

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:20

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

13 SEP 2020 14:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:56

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 16:54

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 18:21

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**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

10 SEP 2020 17:05

PC Open Date & Time

10 SEP 2020 16:53

PC Close Date & Time

10 SEP 2020 19:23



US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**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 ☐

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

26

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)**

35

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 10:17

PC Open Date & Time

10 SEP 2020 20:18

PC Close Date & Time

11 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**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)**

64

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)**

64

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

11 SEP 2020 18:58

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**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 ☐

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

74

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)**

74

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

12 SEP 2020 12:23

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**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 ☐

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

76

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)**

76

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

13 SEP 2020 14:47

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**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 ☐

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

52

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)**

67

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

14 SEP 2020 12:57

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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

33

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

15 SEP 2020 16:55

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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

26

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

16 SEP 2020 18:22

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**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 ☐



US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 17:05
PC Open Date & Time	10 SEP 2020 16:53
PC Close Date & Time	10 SEP 2020 19:23

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**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 ☐

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 10:18
PC Open Date & Time	10 SEP 2020 20:18
PC Close Date & Time	11 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**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 ☒

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:58
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:23
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

103 of 2129

EAB) (1725)



US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 14:48
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or  
1-2 episodes/24 hours ☐

Some interference with activity  
or >2 episodes/24 hours ☐

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 2129

EAB) (1725)

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:57
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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 ☒

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 16:55
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**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 ☒

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US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:22
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT

DAY 8

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.

PC Time stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59



US3152162

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(9)

Generated On: 09 Jun 2021 15:27:55

<b>TIMEPOINT</b>	DAY 9
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
PC Time stamp	18 SEP 2020 12:22
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3152162

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:27:55

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 12:23
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3152162

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3152162

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3152162

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:42:40

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3152162

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:42:40

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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

US3152162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	14:11 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 14:11
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3152162

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

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.*

US3152162

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	14:19 (24 HR)
Collection date and time (derived)	9 OCT 2020 14:19

US3152162

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:10:57

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	16 OCT 2020 13:56:20
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 13:24:21

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59



US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	28 OCT 2020 00:01:47
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 16:22:25

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 NOV 2020 11:51:47
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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

21 NOV 2020 00:14:09

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2020 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 DEC 2020 13:25:51

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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	12 DEC 2020 00:36:57
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59



US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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

21 DEC 2020 10:40:51

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 DEC 2020 21:05:41

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 00:08:41

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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 <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	10 JAN 2021 07:53:05
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 22:06:59
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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

27 JAN 2021 12:27:01

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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

30 JAN 2021 01:02:14

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 08:14:31
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59



US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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 <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 10:31:26
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 FEB 2021 09:51:05
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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

27 FEB 2021 11:13:14

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 15:36:29

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 10:25:04

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 14:02:20

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

Date and time of submission

27 MAR 2021 00:01:40

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 APR 2021 12:02:22
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59



US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 APR 2021 10:35:51
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 APR 2021 16:23:42
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

Date and time of submission

25 APR 2021 15:10:50

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 00:26:52
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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°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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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



US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUL 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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°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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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 <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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59
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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	04 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59
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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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 <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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59



US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 530

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	29 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 FEB 2022 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 544

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 FEB 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 FEB 2022 23:59
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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this 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



US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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°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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59



US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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°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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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



US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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="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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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°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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 684

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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="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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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"/>

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**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 ☐

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3152162

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3152162**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

**US3152162**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 15:27:55**

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 11:14:03

US3152162

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 12:55:00

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3152162

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 12:55:00

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3152162

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3152162

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3152162

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:11:43

Generated On: 09 Jun 2021 15:27:55

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 VISIT4

US3152162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 17:11:43

Generated On: 09 Jun 2021 15:27:55

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

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

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3152162

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

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.*



US3152162

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3152162

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152162

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3152162

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3152162**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3152162**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3152162**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:27:55**

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

**US3152162**

**Folder: Covid-19 Assessment (1)**

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

**Generated On: 09 Jun 2021 15:27:55**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3152162

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

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

Visit date (dd MMM yyyy)	01 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3152162

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Date of updated informed consent (dd MMM yyyy) 01 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 01 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3152162

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 FEB 2021

Collection time (00:00-23:59)

10:33 (24 HR)

Collection date and time (derived)

01 FEB 2021 10:33

US3152162

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

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

Collection date (dd MMM yyyy)	01 FEB 2021
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Collection time (00:00 - 23:59)	10:42
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Collection Date and Time (derived)	01 FEB 2021 10:42
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US3152162

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Mar 2021 02:02:28

Generated On: 09 Jun 2021 15:27:55

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3152162

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

AEID

Adverse event

URINARY 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)

28 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

333 of 2129

EAB) (1725)

US3152162

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

AEID	USA-US073-2021-MRNA-1273-P30 1000011
Adverse event	ACUTE CEREBROVASCULAR ACCIDENT
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)	01 APR 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)	01 APR 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	01 APR 2021
Hospital Discharge Date (dd MMM yyyy)	03 APR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Data signed: (b) (4) 28 Apr 2021 17:11:18

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Number of Days in ICU	1
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	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	

US3152162

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

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01 APR 2021 SUBJECT AWOKE WITH DIPLOPIA AND MILD HEADACHE. ULTIMATELY REFERRED TO EMERGENCY ROOM BY PRIMARY CARE PROVIDER. MRI/MRA (01 APR) IMPRESSION 5MM REGION OF MILDLY DIFFUSE BRIGHT SIGNAL/DARK ADC SIGNAL WITHIN THE RIGHT INFERIOR PONS WITHOUT UNDERLYING FLAIR HYPERSENSITIVITY WHICH COULD REPRESENT HYPERACUTE INFARCT AND MILD IRREGULARITY OF A LEFT HYPOPLASTIC V4 SEGMENT LEFT HA VERTEBRAL ARTERY OTHERWISE NO SIGNIFICANT STENOSIS OR ANEURYSM GREATER THAN 3MM. FINAL DIAGNOSIS ACUTE CEREBROVASCULAR ACCIDENT. TISSUE PLASMINOGEN ACTIVATOR ADMINISTERED. SUBJECT THEN ADMITTED TO ICU FOR OBSERVATION. DISCHARGED 03 APR 2021. RELEVANT STUDIES: CBC WITH DIF, CMP, MAGNESIUM, TROPONIN, TSH, APPT/PT/INR WITHIN NORMAL LIMITS. SARS COV-2 NEGATIVE (01 APR 2021). CAROTID DOPPLER (01 APR

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

2021) IMPRESSION- NEGATIVE  
EXAM NO PLAQUE OR  
VELOCITY ELEVATION SEEN.  
TRANSTHORACIC ECHO WITH  
BUBBLE STUDY (01 APR 2021)  
IMPRESSION- LEFT  
VENTRICULAR EJECTION  
FRACTION NORMAL  
ESTIMATED RANGE OF 60-65%,  
LEFT VENTRICULAR CAVITY  
SIZE APPEARS NORMAL, LEFT  
VENTRICULAR WALL  
THICKNESS APPEARS NORMAL,  
UNABLE TO OBTAIN RVSP DUE  
TO INSUFFICIENT TRICUSPID  
REGURGITATION JET, THERE IS  
NO SIGNIFICANT VALVE  
DISEASE, BUBBLE STUDY IS  
INADEQUATE TO EVALUATE  
THE ATRIAL SEPTUM, NO  
OBVIOUS SOURCE OF  
EMBOLISM. EKG 12 LEAD (01  
APR 2021) SINUS  
TACHYCARDIA WHEN  
COMPARED TO EKG 04 MAY  
2018 INCOMPLETE RIGHT  
BUNDLE BRANCH BLOCK NO  
LONGER PRESENT T WAVE  
INVERSION NO LONGER  
EVIDENT IN INFERIOR LEADS .  
NARRATIVE UPDATED AFTER  
MEDICAL RECORDS RECEIVED  
AND REVIEWED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

AEID	
Adverse event	POST TRAUMATIC STRESS DISORDER
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)	8 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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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	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 02:12:20

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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Name of Medication LAMICTAL

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR DISORDER

Dose per administration 150

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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US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

	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 2001	
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)	2	
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) 28 Apr 2021 17:11:18

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Name of Medication BU PROPION HCL

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 150

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 (2)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

	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 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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Name of Medication ALBUTEROL HCL

Prophylaxis Yes ☐  
No ☒

Indication MILD ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1984	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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Name of Medication NITROFURANTOIN MONO

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

	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)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	3 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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Name of Medication	INFLUENZA VACCINATION
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PROPHYLAXIS FOR INFLUENZA VIRUS
Dose per administration	0.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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Name of Medication TISSUE PLASMINOGEN  
ACTIVATOR

Prophylaxis Yes ☐  
No ☒

Indication ACUTE CEREBROVASCULAR  
ACCIDENT

Dose per administration 85.1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 APR 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 (7)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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Name of Medication PLAVIX

Prophylaxis Yes ☒  
No ☐

Indication CEREBROVASCULAR  
ACCIDENT PROPHYLAXIS

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 17:11:18

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	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)	03 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CEREBROVASCULAR  
ACCIDENT PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

	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)		03 APR 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"/>

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

Name of Medication LIPITOR

Prophylaxis Yes ☒  
No ☐

Indication CEREBROVASCULAR  
ACCIDENT PROPHYLAXIS

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 APR 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"/>



US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

Name of Medication TOPAMAX

Prophylaxis Yes ☐  
No ☒

Indication POST TRAUMATIC STRESS  
DISORDER, DEPRESSION,  
BIPOLAR DISORDER

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

	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 APR 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"/>

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

Name of Medication PRAZOSIN

Prophylaxis Yes ☐  
No ☒

Indication POST TRAUMATIC STRESS  
DISORDER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

	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)		21 APR 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"/>

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

Name of Medication ZOLPIDEM

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

	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 2001	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

Name of Medication VALACYCLOVIR

Prophylaxis Yes ☐  
No ☒

Indication HERPES LABIALIS

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 17:11:18

Generated On: 09 Jun 2021 15:27:55

	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 1984	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3152162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Apr 2021 21:09:55

Generated On: 09 Jun 2021 15:27:55

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3152162

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:27:55

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

US3152162

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:27:55

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 ☐

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

SAEID	USA-US073-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

SAEID	USA-US073-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	06/APR/2021 12:01
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

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

SAEID	USA-US073-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/APR/2021 10:09
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

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 17:11:19

Generated On: 09 Jun 2021 15:27:55

SAEID	USA-US073-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input 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	BRANDON
Investigator's Last Name	ESSINK
Site Address: Street	3319 N 107TH
Site Address: City	OMAHA
Site Address: State	
Site Address: Postal Code	68134
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/APR/2021 15:22
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

US3152162 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)



**US3152162**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:27:55**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'US3152162'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:39:30

**US3152162**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	13 Aug 2020 17:35:52

**US3152162**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:39:31

**US3152162**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[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 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Clinic (Clinic)'	Jemario Blackwell (b) (4) (b) (4)	13 Aug 2020 17:35:52

**US3152162**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'SCRN'	System	13 Aug 2020 17:35:52

US3152162

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered (b) (6) 1974'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:39:32

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '46'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'YEARS'	System	13 Aug 2020 17:36:21



**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '46'	System	13 Aug 2020 17:36:40

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Female (F)'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'I'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Jemario Blackwell (b) (4) (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21



**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Jemario Blackwell (b) (4) (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:55**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:21

**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	Jemario Blackwell (b) (4) (b) (4)	13 Aug 2020 17:36:40

**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Aug 2020'	System	13 Aug 2020 17:36:40

**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '2020'	System	13 Aug 2020 17:36:40

**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Amendment 2 (2)'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:40



**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:40

**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Jemario Blackwell (b) (4) (b) (4)	13 Aug 2020 17:36:40

**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:40

**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:40

**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:39:31

**US3152162**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:55**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'I'	System	13 Aug 2020 17:36:46

**US3152162**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	13 Aug 2020 17:36:46

**US3152162**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 15:27:55**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:35:42



US3152162

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User coded data point as SOC: Psychiatric disorders, HLG: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 03:27:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 03:27:16
Data point term sent to Coder	System	14 Aug 2020 00:37:00
User entered 'BIPOLOAR DISORDER'	(b) (4), (b) (6)	14 Aug 2020 00:36:01

**US3152162**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'UN UNK 2001'	(b) (4), (b) (6)	14 Aug 2020 00:36:01

**US3152162**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:36:01

**US3152162**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:36:01

**US3152162**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:36:01

**US3152162**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:36:01

**US3152162**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 2001'	System	14 Aug 2020 00:36:01

**US3152162**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '2001'	System	14 Aug 2020 00:36:01



**US3152162**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	14 Aug 2020 00:36:01

**US3152162**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	14 Aug 2020 00:36:01

US3152162

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 00:38:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 00:38:19
Data point term sent to Coder	System	14 Aug 2020 00:37:00
User entered 'DEPRESSION'	(b) (4), (b) (6)	14 Aug 2020 00:36:17

**US3152162**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'UN UNK 2018'	(b) (4), (b) (6)	14 Aug 2020 00:36:17

**US3152162**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:36:17

**US3152162**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:36:17

**US3152162**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:36:17

**US3152162**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:36:17



**US3152162**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 2018'	System	14 Aug 2020 00:36:17

**US3152162**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '2018'	System	14 Aug 2020 00:36:17

**US3152162**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	14 Aug 2020 00:36:17

**US3152162**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	14 Aug 2020 00:36:17

US3152162

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 00:38:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 00:38:20
Data point term sent to Coder	System	14 Aug 2020 00:37:01
User entered 'MILD ASTHMA'	(b) (4), (b) (6)	14 Aug 2020 00:36:29

**US3152162**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'UN UNK 1984'	(b) (4), (b) (6)	14 Aug 2020 00:36:29

**US3152162**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:36:29

**US3152162**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:36:29



**US3152162**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:36:29

**US3152162**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:36:29

**US3152162**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 1984'	System	14 Aug 2020 00:36:29

**US3152162**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '1984'	System	14 Aug 2020 00:36:29

**US3152162**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	14 Aug 2020 00:36:29

**US3152162**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	14 Aug 2020 00:36:29

US3152162

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine leiomyoma - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:13:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:13:42
Data point term sent to Coder	System	14 Sep 2020 16:12:34
User entered 'uterine leiomyoma'	Tanya Alexander (b) (4)	14 Sep 2020 16:11:42

**US3152162**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'un UNK 2018'	Tanya Alexander (b) (4)	14 Sep 2020 16:11:42



**US3152162**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Tanya Alexander (b) (4)	14 Sep 2020 16:11:42

**US3152162**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	Tanya Alexander (b) (4)	14 Sep 2020 16:11:42

**US3152162**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'un UNK 2018'	Tanya Alexander (b) (4)	14 Sep 2020 16:11:42

**US3152162**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Tanya Alexander (b) (4)	14 Sep 2020 16:11:42

**US3152162**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 2018'	System	14 Sep 2020 16:11:42

**US3152162**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '2018'	System	14 Sep 2020 16:11:42

**US3152162**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 2018'	System	14 Sep 2020 16:11:42

**US3152162**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '2018'	System	14 Sep 2020 16:11:42



US3152162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:13:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:13:41
Data point term sent to Coder	System	14 Sep 2020 16:12:34
User entered 'hysterectomy'	Tanya Alexander (b) (4)	14 Sep 2020 16:12:16

US3152162

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
Query 'Per CDM: Please consider updating Start Date to UN JAN 2018. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 17:51:46
User opened query 'Per CDM: Please consider updating Start Date to UN JAN 2018. Thank you.' (Site from DM).		25 Sep 2020 17:51:30
User entered 'un UNK 2018'	Tanya Alexander (b) (4) (b) (4)	14 Sep 2020 16:12:16

**US3152162**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Tanya Alexander (b) (4)	14 Sep 2020 16:12:16

**US3152162**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	Tanya Alexander (b) (4)	14 Sep 2020 16:12:16

**US3152162**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'un UNK 2018'	Tanya Alexander (b) (4)	14 Sep 2020 16:12:16

**US3152162**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Tanya Alexander (b) (4)	14 Sep 2020 16:12:16

**US3152162**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 2018'	System	14 Sep 2020 16:12:16

**US3152162**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '2018'	System	14 Sep 2020 16:12:16



**US3152162**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 2018'	System	14 Sep 2020 16:12:16

**US3152162**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '2018'	System	14 Sep 2020 16:12:16

US3152162

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 19:51:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Feb 2021 19:51:47
Data point term sent to Coder	System	08 Feb 2021 19:50:59
User entered 'postmenopausal'	Juliana DeVito (b) (4)	08 Feb 2021 19:50:16
	(b) (4)	

**US3152162**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'un UNK 2018'	Juliana DeVito (b) (4)	08 Feb 2021 19:50:16

**US3152162**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Juliana DeVito (b) (4)	08 Feb 2021 19:50:16

**US3152162**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	08 Feb 2021 19:50:16

**US3152162**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Juliana DeVito (b) (4)	08 Feb 2021 19:50:16

**US3152162**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	Juliana DeVito (b) (4)	08 Feb 2021 19:50:16



**US3152162**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 2018'	System	08 Feb 2021 19:50:16

**US3152162**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '2018'	System	08 Feb 2021 19:50:16

**US3152162**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	08 Feb 2021 19:50:16

**US3152162**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	08 Feb 2021 19:50:16

US3152162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 18:56:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 18:56:17
Data point term sent to Coder	System	23 Apr 2021 18:54:47
User entered 'INSOMNIA'	(b) (4), (b) (6)	23 Apr 2021 18:54:14

**US3152162**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'UN UNK 2001'	(b) (4), (b) (6)	23 Apr 2021 18:54:14

**US3152162**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 18:54:14

US3152162

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:54:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 18:54:21
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 18:54:21
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:54:14
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:54:14



**US3152162**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:54:14

**US3152162**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 18:54:14

**US3152162**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 2001'	System	23 Apr 2021 18:54:14

**US3152162**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '2001'	System	23 Apr 2021 18:54:14

**US3152162**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	23 Apr 2021 18:54:14

**US3152162**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	23 Apr 2021 18:54:14

US3152162

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Oral herpes, LLT: Herpes labialis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 18:57:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 18:57:02
Data point term sent to Coder	System	23 Apr 2021 18:55:59
User entered 'Herpes labialis'	(b) (4), (b) (6)	23 Apr 2021 18:55:03

**US3152162**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'UN UNK 1984'	(b) (4), (b) (6)	23 Apr 2021 18:55:03



**US3152162**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 18:55:03

**US3152162**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:55:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 18:55:09
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 18:55:09
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:55:03
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:55:03

**US3152162**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:55:03

**US3152162**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 18:55:03

**US3152162**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'Jan 1984'	System	23 Apr 2021 18:55:03

**US3152162**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '1984'	System	23 Apr 2021 18:55:03

**US3152162**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	23 Apr 2021 18:55:03

**US3152162**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	23 Apr 2021 18:55:03



**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '11:20'	(b) (4), (b) (6)	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered '13 Aug 2020 11:20'	System	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '160.7' cm	(b) (4), (b) (6)	14 Aug 2020 00:37:36
DataPoint set to visible.	System	13 Aug 2020 17:36:46

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '95.5' kg	(b) (4), (b) (6)	14 Aug 2020 00:37:36
DataPoint set to visible.	System	13 Aug 2020 17:36:46

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
Amendment Manager: User entered '36.98040'	System	16 Sep 2020 23:55:18
User entered '37.0'	System	14 Aug 2020 00:37:36
DataPoint set to visible.	System	13 Aug 2020 17:36:46

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'kg/m2'	System	14 Aug 2020 00:37:36
DataPoint set to visible.	System	13 Aug 2020 17:36:46



US3152162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:56:57
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' answered with 'done' (Site from DM).	Juliana DeVito (b) (4) (b) (4)	12 Sep 2020 13:24:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4) (b) (4)	12 Sep 2020 13:24:02
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	30 Aug 2020 09:24:51
User entered '37.1' C		14 Aug 2020 00:37:36

US3152162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:24:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:24:02
User entered '81'	(b) (4), (b) (6)	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'bpm'	System	14 Aug 2020 00:37:36

US3152162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:24:02
User entered '15'	(b) (4), (b) (6)	14 Aug 2020 00:37:36

US3152162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'breaths/min'	System	14 Aug 2020 00:37:36

US3152162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:24:02
User entered '129'	(b) (4), (b) (6)	14 Aug 2020 00:37:36



**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'mmHg'	System	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:24:02
User entered '89'	(b) (4), (b) (6)	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered 'mmHg'	System	14 Aug 2020 00:37:36

**US3152162**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47

US3152162

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47

**US3152162**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:27:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:37:46

US3152162

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		30 Sep 2020 21:32:33
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 14:01:34
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:37:46

**US3152162**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:27:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:38:40



US3152162

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:55

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)' reason for change: New Information	Tanya Alexander (b) (4)	14 Sep 2020 16:12:35
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	14 Aug 2020 00:38:57
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	14 Aug 2020 00:38:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:38:40

US3152162

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:55

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:12:45
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: New Information	Tanya Alexander (b) (4)	14 Sep 2020 16:12:45
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:12:35
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:38:40

**US3152162**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:38:40

US3152162

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:12:58
User entered 'un UNK 2018' reason for change: Data Entry Error	Tanya Alexander (b) (4)	14 Sep 2020 16:12:58
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	(b) (4)	14 Sep 2020 16:12:45
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:38:40

**US3152162**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:27:55**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:38:40

**US3152162**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:38:40

**US3152162**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:27:55**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 00:38:57
User entered '1'		14 Aug 2020 00:38:40

**US3152162**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:39:13



**US3152162**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:39:13

**US3152162**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Urine (URINE)'	(b) (4), (b) (6)	14 Aug 2020 00:39:13

**US3152162**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	14 Aug 2020 00:39:13

**US3152162**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:13

**US3152162**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:39:13

**US3152162**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:39:13

**US3152162**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User entered empty.	System	14 Aug 2020 00:39:13

**US3152162**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58



US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

**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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

**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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

[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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

**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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

**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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

**US3152162**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:27:55**

**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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58



US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

**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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

**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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 16:10:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 16:10:20
User entered 'No (N)' reason for change: Per Query Resolution	Tanya Alexander (b) (4)	14 Sep 2020 16:10:20
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 00:39:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:39:58

**US3152162**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:27:55**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:39:58

**US3152162**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:27:55**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

**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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

[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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:39:58



US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

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)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

US3152162

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'I'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

**US3152162**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:27:55**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:39:58

**US3152162**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:27:55**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:01:47
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:39:58

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:40:12

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:40:12

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Aug 2020 00:40:12

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'VISIT1'	System	14 Aug 2020 00:40:12



US3152162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:24:46

US3152162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:10:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:10:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:24:46
User entered '103810' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:24:46

US3152162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:24:46

US3152162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:55

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)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User closed query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:17:57
Query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' answered with 'done' (Site from DM).	Tanya Alexander (b) (4)	14 Sep 2020 16:09:19
User entered 'No (N)'	Azure Erskine (b) (4)	04 Sep 2020 18:29:16
User opened query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:57:54

US3152162

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:55

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)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	Azure Erskine (b) (4)	04 Sep 2020 18:29:16

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	Azure Erskine (b) (4)	04 Sep 2020 18:29:16

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:27:55**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	Azure Erskine (b) (4)	04 Sep 2020 18:29:16

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:27:55**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	Azure Erskine (b) (4)	04 Sep 2020 18:29:16



**US3152162**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 17:41:54
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:40
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:01:12

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:08:00
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 13:22:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Sep 2020 13:22:54
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:43:36
User entered '160.7' cm		14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:22:54
User entered '95.5' kg	(b) (4), (b) (6)	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:08:00
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 13:22:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Sep 2020 13:22:54
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:43:36
User entered '160.7' cm		14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:22:54
User entered '95.5' kg	(b) (4), (b) (6)	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User accepted default value 'Pre-Dose (PREDOSE)'		14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:42:25



**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '11:20'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '13 Aug 2020 11:20'	System	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '37.1' C	(b) (4), (b) (6)	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '81'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'bpm'	System	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '15'	(b) (4), (b) (6)	14 Aug 2020 00:42:25



US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'breaths/min'	System	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '129'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '89'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:08:00
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 13:22:58
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Sep 2020 13:22:54
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:43:36
User entered '160.7' cm		14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:22:54
User entered '95.5' kg	(b) (4), (b) (6)	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User accepted default value 'Post-Dose (POSTDOSE)'		14 Aug 2020 00:42:25



US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 09:12:10
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		14 Aug 2020 00:42:25
User entered '13:34'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '13 Aug 2020 13:34'	System	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '37.1' C	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '84'	(b) (4), (b) (6)	14 Aug 2020 00:42:25



**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'bpm'	System	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '14'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'breaths/min'	System	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '132'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	14 Aug 2020 00:42:25

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '84'	(b) (4), (b) (6)	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	14 Aug 2020 00:42:25

US3152162

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)' reason for change: Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:23:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:42:34



**US3152162**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:27:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:23:20
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:42:34

US3152162

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:27:55

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:39:48
Query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 13:23:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Sep 2020 13:23:35
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' (Site from DM).	Ipsita Abalokita (b) (4)	10 Sep 2020 08:30:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:42:50

US3152162

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:27:55

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:23:35
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:42:50

US3152162

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:27:55

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:23:35
User entered 'Urine (URINE)'	(b) (4), (b) (6)	14 Aug 2020 00:42:50

US3152162

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:27:55

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:23:35
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	14 Aug 2020 00:42:50

US3152162

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:27:55

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 13:23:35
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:42:50

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:42:50

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:42:50



**US3152162**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered empty.	System	14 Aug 2020 00:42:50

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:55**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	13 Aug 2020 17:37:22

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:55**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Jemario Blackwell (b) (4)	13 Aug 2020 17:37:22

US3152162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

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)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Jemario Blackwell (b) (4)	13 Aug 2020 17:37:22

US3152162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:37:22

US3152162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	Jemario Blackwell (b) (4)	13 Aug 2020 17:37:22

US3152162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13:02'	Jemario Blackwell (b) (4)	13 Aug 2020 17:37:22

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '13 Aug 2020 13:02'	System	13 Aug 2020 17:37:22



US3152162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Left Arm (LEFT ARM)'	Jemario Blackwell (b) (4)	13 Aug 2020 17:37:22

US3152162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'ONCE'	System	13 Aug 2020 17:37:22

US3152162

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:37:22

US3152162

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:43:17

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:43:17

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '11:49'	(b) (4), (b) (6)	14 Aug 2020 00:43:17

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '13 Aug 2020 11:49'	System	14 Aug 2020 00:43:17

US3152162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '13 Aug 2020'	(b) (4), (b) (6)	14 Aug 2020 00:43:40



**US3152162**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Aug 2020 00:43:40

US3152162

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:43:40

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '12:11'	(b) (4), (b) (6)	14 Aug 2020 00:43:40

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '13 Aug 2020 12:11'	System	14 Aug 2020 00:43:40

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		14 Aug 2020 00:43:40

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:43:40

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:43:40

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered empty.	System	14 Aug 2020 00:43:40



**US3152162**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:43:47

**US3152162**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '1'	System	14 Aug 2020 00:43:47

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:38:05', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '70ef665b-f0d4-4025-9f4f-332532a498a9'	System	13 Aug 2020 17:38:26
User entered 'Yes (Y)'	System	13 Aug 2020 17:38:26

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:38:12', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '70ef665b-f0d4-4025-9f4f-332532a498a9' User entered '98.9'	System	13 Aug 2020 17:38:26
	System	13 Aug 2020 17:38:26

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:38:16', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '70ef665b-f0d4-4025-9f4f-332532a498a9'	System	13 Aug 2020 17:38:26
User entered 'No (N)'	System	13 Aug 2020 17:38:26

**US3152162**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:38:23', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '70ef665b-f0d4-4025-9f4f-332532a498a9'	System	13 Aug 2020 17:38:26
User entered '13 Aug 2020 13:38'	System	13 Aug 2020 17:38:26

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Aug 2020 13:22'	System	13 Aug 2020 17:37:22



US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Aug 2020 15:52'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:52:55', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b416ca2d-f13a-41ce-8b50-d0e66f9d222f'	System	13 Aug 2020 23:54:34
User entered 'Yes (Y)'	System	13 Aug 2020 23:54:34

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:54:18', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b416ca2d-f13a-41ce-8b50-d0e66f9d222f' User entered '98.0'	System	13 Aug 2020 23:54:34
	System	13 Aug 2020 23:54:34

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:54:22', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b416ca2d-f13a-41ce-8b50-d0e66f9d222f'	System	13 Aug 2020 23:54:34
User entered 'No (N)'	System	13 Aug 2020 23:54:34

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:54:29', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b416ca2d-f13a-41ce-8b50-d0e66f9d222f'	System	13 Aug 2020 23:54:34
User entered '13 Aug 2020 19:54'	System	13 Aug 2020 23:54:34

**US3152162**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Aug 2020 16:47'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:37:22



US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 2'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:49:56', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '064f3a1e-4c41-48aa-bd47-4ca322bf15e6'	System	14 Aug 2020 16:51:40
User entered 'Yes (Y)'	System	14 Aug 2020 16:51:40

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:51:22', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '064f3a1e-4c41-48aa-bd47-4ca322bf15e6'	System	14 Aug 2020 16:51:40
User entered '98.6'	System	14 Aug 2020 16:51:40

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:51:29', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '064f3a1e-4c41-48aa-bd47-4ca322bf15e6'	System	14 Aug 2020 16:51:40
User entered 'No (N)'	System	14 Aug 2020 16:51:40

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:51:35', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '064f3a1e-4c41-48aa-bd47-4ca322bf15e6'	System	14 Aug 2020 16:51:40
User entered '14 Aug 2020 12:51'	System	14 Aug 2020 16:51:40

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 3'	System	13 Aug 2020 17:37:22



US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T20:56:44', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'affd1492-a5cc-402b-87da-8883de296846'	System	16 Aug 2020 00:57:01
User entered 'Yes (Y)'	System	16 Aug 2020 00:57:01

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T20:56:51', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'affd1492-a5cc-402b-87da-8883de296846'	System	16 Aug 2020 00:57:01
User entered '98.6'	System	16 Aug 2020 00:57:01

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T20:56:54', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'affd1492-a5cc-402b-87da-8883de296846'	System	16 Aug 2020 00:57:01
User entered 'No (N)'	System	16 Aug 2020 00:57:01

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T20:56:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'affd1492-a5cc-402b-87da-8883de296846'	System	16 Aug 2020 00:57:01
User entered '15 Aug 2020 20:56'	System	16 Aug 2020 00:57:01

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 4'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:45:24', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ead805fc-9457-46b5-9281-bf8275cd4b92'	System	16 Aug 2020 18:45:44
User entered 'Yes (Y)'	System	16 Aug 2020 18:45:44



US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:45:29', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ead805fc-9457-46b5-9281-bf8275cd4b92'	System	16 Aug 2020 18:45:44
User entered '98.6'	System	16 Aug 2020 18:45:44

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:45:40', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ead805fc-9457-46b5-9281-bf8275cd4b92'	System	16 Aug 2020 18:45:44
User entered 'No (N)'	System	16 Aug 2020 18:45:44

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:45:44', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ead805fc-9457-46b5-9281-bf8275cd4b92'	System	16 Aug 2020 18:45:44
User entered '16 Aug 2020 14:45'	System	16 Aug 2020 18:45:44

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 5'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:06:41', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4043e78b-abf6-4a19-9c9f-d2174280cd17'	System	17 Aug 2020 22:06:56
User entered 'Yes (Y)'	System	17 Aug 2020 22:06:56

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:06:46', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4043e78b-abf6-4a19-9c9f-d2174280cd17'	System	17 Aug 2020 22:06:56
User entered '98.4'	System	17 Aug 2020 22:06:56



US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:06:49', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4043e78b-abf6-4a19-9c9f-d2174280cd17'	System	17 Aug 2020 22:06:56
User entered 'No (N)'	System	17 Aug 2020 22:06:56

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:06:52', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4043e78b-abf6-4a19-9c9f-d2174280cd17'	System	17 Aug 2020 22:06:56
User entered '17 Aug 2020 18:06'	System	17 Aug 2020 22:06:56

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 6'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:00:41', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c66fdf50-da3d-4ca4-be9d-de3aba87612a'	System	19 Aug 2020 15:00:56
User entered 'Yes (Y)'	System	19 Aug 2020 15:00:56

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:00:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c66fdf50-da3d-4ca4-be9d-de3aba87612a'	System	19 Aug 2020 15:00:56
User entered '98.4'	System	19 Aug 2020 15:00:56

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:00:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c66fdf50-da3d-4ca4-be9d-de3aba87612a'	System	19 Aug 2020 15:00:56
User entered 'No (N)'	System	19 Aug 2020 15:00:56



**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:00:53', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c66fdf50-da3d-4ca4-be9d-de3aba87612a'	System	19 Aug 2020 15:00:56
User entered '19 Aug 2020 11:00'	System	19 Aug 2020 15:00:56

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 7'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd3bbbedb6-8fc6-44de-84a9-d474b001d08c'	System	20 Aug 2020 15:19:16
User entered 'Yes (Y)'	System	20 Aug 2020 15:19:16

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:05', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd3bbbedb6-8fc6-44de-84a9-d474b001d08c'	System	20 Aug 2020 15:19:16
User entered '98.4'	System	20 Aug 2020 15:19:16

US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:08', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd3bbbedb6-8fc6-44de-84a9-d474b001d08c'	System	20 Aug 2020 15:19:16
User entered 'No (N)'	System	20 Aug 2020 15:19:16

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:12', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd3bbbedb6-8fc6-44de-84a9-d474b001d08c'	System	20 Aug 2020 15:19:16
User entered '20 Aug 2020 11:19'	System	20 Aug 2020 15:19:16



US3152162

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:38:31', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8b77d1b2-fa4c-4ceb-a7ee-158759721d14'	System	13 Aug 2020 17:39:10
User entered 'None (1)'	System	13 Aug 2020 17:39:10

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:38:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8b77d1b2-fa4c-4ceb-a7ee-158759721d14'	System	13 Aug 2020 17:39:10
User entered 'No (N)'	System	13 Aug 2020 17:39:10

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:38:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8b77d1b2-fa4c-4ceb-a7ee-158759721d14'	System	13 Aug 2020 17:39:10
User entered 'No (N)'	System	13 Aug 2020 17:39:10

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:38:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8b77d1b2-fa4c-4ceb-a7ee-158759721d14'	System	13 Aug 2020 17:39:10
User entered 'None (1)'	System	13 Aug 2020 17:39:10

**US3152162**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:39:05', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8b77d1b2-fa4c-4ceb-a7ee-158759721d14'	System	13 Aug 2020 17:39:10
User entered '13 Aug 2020 13:39'	System	13 Aug 2020 17:39:10



**US3152162**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Aug 2020 13:22'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Aug 2020 15:52'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:55:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a287cd34-3fcb-42b7-a5a3-b01e7bf64dca'	System	13 Aug 2020 23:58:10
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 23:58:10

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:55:53', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a287cd34-3fcb-42b7-a5a3-b01e7bf64dca'	System	13 Aug 2020 23:58:10
User entered 'No (N)'	System	13 Aug 2020 23:58:10

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:56:17', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a287cd34-3fcb-42b7-a5a3-b01e7bf64dca'	System	13 Aug 2020 23:58:10
User entered 'Yes (Y)'	System	13 Aug 2020 23:58:10

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:57:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a287cd34-3fcb-42b7-a5a3-b01e7bf64dca'	System	13 Aug 2020 23:58:10
User entered '1'	System	13 Aug 2020 23:58:10

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:57:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a287cd34-3fcb-42b7-a5a3-b01e7bf64dca'	System	13 Aug 2020 23:58:10
User entered 'None (1)'	System	13 Aug 2020 23:58:10



**US3152162**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:58:08', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a287cd34-3fcb-42b7-a5a3-b01e7bf64dca'	System	13 Aug 2020 23:58:10
User entered '13 Aug 2020 19:58'	System	13 Aug 2020 23:58:10

**US3152162**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Aug 2020 16:47'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 2'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:52:06', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'aa4e1be4-e5eb-44f5-9b0d-2b6ca6d002d8'	System	14 Aug 2020 16:53:09
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 16:53:09

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:52:13', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'aa4e1be4-e5eb-44f5-9b0d-2b6ca6d002d8'	System	14 Aug 2020 16:53:09
User entered 'No (N)'	System	14 Aug 2020 16:53:09

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:52:24', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'aa4e1be4-e5eb-44f5-9b0d-2b6ca6d002d8'	System	14 Aug 2020 16:53:09
User entered 'Yes (Y)'	System	14 Aug 2020 16:53:09

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:52:43', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'aa4e1be4-e5eb-44f5-9b0d-2b6ca6d002d8'	System	14 Aug 2020 16:53:09
User entered '3'	System	14 Aug 2020 16:53:09



US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:52:58', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'aa4e1be4-e5eb-44f5-9b0d-2b6ca6d002d8'	System	14 Aug 2020 16:53:09
User entered 'None (1)'	System	14 Aug 2020 16:53:09

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:53:05', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'aa4e1be4-e5eb-44f5-9b0d-2b6ca6d002d8'	System	14 Aug 2020 16:53:09
User entered '14 Aug 2020 12:53'	System	14 Aug 2020 16:53:09

**US3152162**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 3'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:01:43', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8be8389d-5ea3-4585-a4f7-5799d14d9493'	System	16 Aug 2020 01:02:11
User entered 'None (1)'	System	16 Aug 2020 01:02:11

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:01:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8be8389d-5ea3-4585-a4f7-5799d14d9493'	System	16 Aug 2020 01:02:11
User entered 'No (N)'	System	16 Aug 2020 01:02:11

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:01:55', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8be8389d-5ea3-4585-a4f7-5799d14d9493'	System	16 Aug 2020 01:02:11
User entered 'No (N)'	System	16 Aug 2020 01:02:11



US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:01:58', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8be8389d-5ea3-4585-a4f7-5799d14d9493'	System	16 Aug 2020 01:02:11
User entered 'None (1)'	System	16 Aug 2020 01:02:11

**US3152162**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:02:09', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8be8389d-5ea3-4585-a4f7-5799d14d9493'	System	16 Aug 2020 01:02:11
User entered '15 Aug 2020 21:02'	System	16 Aug 2020 01:02:11

**US3152162**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 4'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:23', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2f4cfb69-adc8-471b-bb03-81463b7008d2'	System	16 Aug 2020 18:46:39
User entered 'None (1)'	System	16 Aug 2020 18:46:39

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:26', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2f4cfb69-adc8-471b-bb03-81463b7008d2'	System	16 Aug 2020 18:46:39
User entered 'No (N)'	System	16 Aug 2020 18:46:39

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:30', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2f4cfb69-adc8-471b-bb03-81463b7008d2'	System	16 Aug 2020 18:46:39
User entered 'No (N)'	System	16 Aug 2020 18:46:39



US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:33', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2f4cfb69-adc8-471b-bb03-81463b7008d2'	System	16 Aug 2020 18:46:39
User entered 'None (1)'	System	16 Aug 2020 18:46:39

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:38', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2f4cfb69-adc8-471b-bb03-81463b7008d2'	System	16 Aug 2020 18:46:39
User entered '16 Aug 2020 14:46'	System	16 Aug 2020 18:46:39

**US3152162**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 5'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:06:56', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '85cfb391-ecce-4cba-8a1d-c977b8f06f2c'	System	17 Aug 2020 22:07:26
User entered 'None (1)'	System	17 Aug 2020 22:07:26

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:06:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '85cfb391-ecce-4cba-8a1d-c977b8f06f2c'	System	17 Aug 2020 22:07:26
User entered 'No (N)'	System	17 Aug 2020 22:07:26

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:04', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '85cfb391-ecce-4cba-8a1d-c977b8f06f2c'	System	17 Aug 2020 22:07:26
User entered 'No (N)'	System	17 Aug 2020 22:07:26



US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:07', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '85cfb391-ecce-4cba-8a1d-c977b8f06f2c'	System	17 Aug 2020 22:07:26
User entered 'None (1)'	System	17 Aug 2020 22:07:26

**US3152162**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:21', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '85cfb391-ecce-4cba-8a1d-c977b8f06f2c'	System	17 Aug 2020 22:07:26
User entered '17 Aug 2020 18:07'	System	17 Aug 2020 22:07:26

**US3152162**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 6'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:00:58', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8af536e2-e1d8-4dbe-afad-dc3d2162b250'	System	19 Aug 2020 15:01:12
User entered 'None (1)'	System	19 Aug 2020 15:01:12

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:01', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8af536e2-e1d8-4dbe-afad-dc3d2162b250'	System	19 Aug 2020 15:01:12
User entered 'No (N)'	System	19 Aug 2020 15:01:12

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8af536e2-e1d8-4dbe-afad-dc3d2162b250'	System	19 Aug 2020 15:01:12
User entered 'No (N)'	System	19 Aug 2020 15:01:12



US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:06', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8af536e2-e1d8-4dbe-afad-dc3d2162b250'	System	19 Aug 2020 15:01:12
User entered 'None (1)'	System	19 Aug 2020 15:01:12

**US3152162**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:11', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8af536e2-e1d8-4dbe-afad-dc3d2162b250'	System	19 Aug 2020 15:01:12
User entered '19 Aug 2020 11:01'	System	19 Aug 2020 15:01:12

**US3152162**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 7'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:18', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '26c17be9-410d-4bda-b209-3df61d733404'	System	20 Aug 2020 15:19:36
User entered 'None (1)'	System	20 Aug 2020 15:19:36

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:20', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '26c17be9-410d-4bda-b209-3df61d733404'	System	20 Aug 2020 15:19:36
User entered 'No (N)'	System	20 Aug 2020 15:19:36

US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:26', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '26c17be9-410d-4bda-b209-3df61d733404'	System	20 Aug 2020 15:19:36
User entered 'No (N)'	System	20 Aug 2020 15:19:36



US3152162

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:28', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '26c17be9-410d-4bda-b209-3df61d733404'	System	20 Aug 2020 15:19:36
User entered 'None (1)'	System	20 Aug 2020 15:19:36

**US3152162**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:31', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '26c17be9-410d-4bda-b209-3df61d733404'	System	20 Aug 2020 15:19:36
User entered '20 Aug 2020 11:19'	System	20 Aug 2020 15:19:36

**US3152162**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:39:10', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4f780eae-a4fa-40bc-81ff-140ef8161539'	System	13 Aug 2020 17:39:41
User entered 'None (0)'	System	13 Aug 2020 17:39:41

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:39:17', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4f780eae-a4fa-40bc-81ff-140ef8161539'	System	13 Aug 2020 17:39:41
User entered 'None (0)'	System	13 Aug 2020 17:39:41

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:39:20', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4f780eae-a4fa-40bc-81ff-140ef8161539'	System	13 Aug 2020 17:39:41
User entered 'None (0)'	System	13 Aug 2020 17:39:41



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:39:23', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4f780eae-a4fa-40bc-81ff-140ef8161539'	System	13 Aug 2020 17:39:41
User entered 'None (0)'	System	13 Aug 2020 17:39:41

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:39:25', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4f780eae-a4fa-40bc-81ff-140ef8161539'	System	13 Aug 2020 17:39:41
User entered 'None (0)'	System	13 Aug 2020 17:39:41

**US3152162**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:39:28', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4f780eae-a4fa-40bc-81ff-140ef8161539'	System	13 Aug 2020 17:39:41
User entered 'None (0)'	System	13 Aug 2020 17:39:41

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:39:32', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4f780eae-a4fa-40bc-81ff-140ef8161539'	System	13 Aug 2020 17:39:41
User entered 'No (N)'	System	13 Aug 2020 17:39:41

**US3152162**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T13:39:38', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4f780eae-a4fa-40bc-81ff-140ef8161539'	System	13 Aug 2020 17:39:41
User entered '13 Aug 2020 13:39'	System	13 Aug 2020 17:39:41

**US3152162**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Aug 2020 13:22'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Aug 2020 15:52'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:37:22



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:58:27', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '762942e3-1966-406f-ad4f-a20f64f07da1'	System	13 Aug 2020 23:59:21
User entered 'None (0)'	System	13 Aug 2020 23:59:21

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:58:46', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '762942e3-1966-406f-ad4f-a20f64f07da1'	System	13 Aug 2020 23:59:21
User entered 'Some interference with activity (2)'	System	13 Aug 2020 23:59:21

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:58:49', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '762942e3-1966-406f-ad4f-a20f64f07da1'	System	13 Aug 2020 23:59:21
User entered 'None (0)'	System	13 Aug 2020 23:59:21

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:58:52', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '762942e3-1966-406f-ad4f-a20f64f07da1'	System	13 Aug 2020 23:59:21
User entered 'None (0)'	System	13 Aug 2020 23:59:21

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:58:54', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '762942e3-1966-406f-ad4f-a20f64f07da1'	System	13 Aug 2020 23:59:21
User entered 'None (0)'	System	13 Aug 2020 23:59:21

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:59:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '762942e3-1966-406f-ad4f-a20f64f07da1'	System	13 Aug 2020 23:59:21
User entered 'None (0)'	System	13 Aug 2020 23:59:21

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:59:09', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '762942e3-1966-406f-ad4f-a20f64f07da1'	System	13 Aug 2020 23:59:21
User entered 'No (N)'	System	13 Aug 2020 23:59:21

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-13T19:59:18', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '762942e3-1966-406f-ad4f-a20f64f07da1'	System	13 Aug 2020 23:59:21
User entered '13 Aug 2020 19:59'	System	13 Aug 2020 23:59:21



**US3152162**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Aug 2020 16:47'	System	13 Aug 2020 17:37:22

**US3152162**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 2'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:53:10', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'df548b52-e9f0-4f05-860d-75d71460b60d'	System	14 Aug 2020 16:55:12
User entered 'None (0)'	System	14 Aug 2020 16:55:12

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:54:27', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'df548b52-e9f0-4f05-860d-75d71460b60d'	System	14 Aug 2020 16:55:12
User entered 'Some interference with activity (2)'	System	14 Aug 2020 16:55:12

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:54:46', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'df548b52-e9f0-4f05-860d-75d71460b60d'	System	14 Aug 2020 16:55:12
User entered 'No interference with activity (1)'	System	14 Aug 2020 16:55:12

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:54:55', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'df548b52-e9f0-4f05-860d-75d71460b60d' User entered 'None (0)'	System	14 Aug 2020 16:55:12
	System	14 Aug 2020 16:55:12

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:54:57', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'df548b52-e9f0-4f05-860d-75d71460b60d'	System	14 Aug 2020 16:55:12
User entered 'None (0)'	System	14 Aug 2020 16:55:12



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:55:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'df548b52-e9f0-4f05-860d-75d71460b60d' User entered 'None (0)'	System	14 Aug 2020 16:55:12
	System	14 Aug 2020 16:55:12

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:55:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'df548b52-e9f0-4f05-860d-75d71460b60d'	System	14 Aug 2020 16:55:12
User entered 'No (N)'	System	14 Aug 2020 16:55:12

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-14T12:55:09', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'df548b52-e9f0-4f05-860d-75d71460b60d'	System	14 Aug 2020 16:55:12
User entered '14 Aug 2020 12:55'	System	14 Aug 2020 16:55:12

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 3'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:02:24', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'bbaa7d73-5e88-43c4-a296-2c7abbf471ac'	System	16 Aug 2020 01:05:17
User entered 'None (0)'	System	16 Aug 2020 01:05:17

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:02:52', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'bbaa7d73-5e88-43c4-a296-2c7abbf471ac'	System	16 Aug 2020 01:05:17
User entered 'No interference with activity (1)'	System	16 Aug 2020 01:05:17



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:02:56', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'bbaa7d73-5e88-43c4-a296-2c7abbf471ac'	System	16 Aug 2020 01:05:17
User entered 'None (0)'	System	16 Aug 2020 01:05:17

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:02:58', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'bbaa7d73-5e88-43c4-a296-2c7abbf471ac'	System	16 Aug 2020 01:05:17
User entered 'None (0)'	System	16 Aug 2020 01:05:17

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:03:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'bbaa7d73-5e88-43c4-a296-2c7abbf471ac'	System	16 Aug 2020 01:05:17
User entered 'None (0)'	System	16 Aug 2020 01:05:17

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:03:09', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'bbaa7d73-5e88-43c4-a296-2c7abbf471ac'	System	16 Aug 2020 01:05:17
User entered 'None (0)'	System	16 Aug 2020 01:05:17

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:05:06', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'bbaa7d73-5e88-43c4-a296-2c7abbf471ac'	System	16 Aug 2020 01:05:17
User entered 'No (N)'	System	16 Aug 2020 01:05:17

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-15T21:05:16', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'bbaa7d73-5e88-43c4-a296-2c7abbf471ac'	System	16 Aug 2020 01:05:17
User entered '15 Aug 2020 21:05'	System	16 Aug 2020 01:05:17

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:37:22



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 4'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:41', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c773acdc-5a5f-4544-954d-756eeef355c2'	System	16 Aug 2020 18:47:00
User entered 'None (0)'	System	16 Aug 2020 18:47:00

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:43', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c773acdc-5a5f-4544-954d-756eeef355c2'	System	16 Aug 2020 18:47:00
User entered 'None (0)'	System	16 Aug 2020 18:47:00

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c773acdc-5a5f-4544-954d-756eeef355c2'	System	16 Aug 2020 18:47:00
User entered 'None (0)'	System	16 Aug 2020 18:47:00

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c773acdc-5a5f-4544-954d-756eeef355c2'	System	16 Aug 2020 18:47:00
User entered 'None (0)'	System	16 Aug 2020 18:47:00

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:49', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c773acdc-5a5f-4544-954d-756eeef355c2'	System	16 Aug 2020 18:47:00
User entered 'None (0)'	System	16 Aug 2020 18:47:00

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:51', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c773acdc-5a5f-4544-954d-756eeef355c2'	System	16 Aug 2020 18:47:00
User entered 'None (0)'	System	16 Aug 2020 18:47:00

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:46:56', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c773acdc-5a5f-4544-954d-756eeef355c2'	System	16 Aug 2020 18:47:00
User entered 'No (N)'	System	16 Aug 2020 18:47:00



**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-16T14:47:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c773acdc-5a5f-4544-954d-756eeef355c2'	System	16 Aug 2020 18:47:00
User entered '16 Aug 2020 14:47'	System	16 Aug 2020 18:47:00

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 5'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:25', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8a661454-94ae-4d02-8094-3e533d65aa6d'	System	17 Aug 2020 22:07:53
User entered 'None (0)'	System	17 Aug 2020 22:07:53

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:27', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8a661454-94ae-4d02-8094-3e533d65aa6d'	System	17 Aug 2020 22:07:53
User entered 'None (0)'	System	17 Aug 2020 22:07:53

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:29', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8a661454-94ae-4d02-8094-3e533d65aa6d'	System	17 Aug 2020 22:07:53
User entered 'None (0)'	System	17 Aug 2020 22:07:53

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:31', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8a661454-94ae-4d02-8094-3e533d65aa6d' User entered 'None (0)'	System	17 Aug 2020 22:07:53
	System	17 Aug 2020 22:07:53



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:33', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8a661454-94ae-4d02-8094-3e533d65aa6d'	System	17 Aug 2020 22:07:53
User entered 'None (0)'	System	17 Aug 2020 22:07:53

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:35', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8a661454-94ae-4d02-8094-3e533d65aa6d'	System	17 Aug 2020 22:07:53
User entered 'None (0)'	System	17 Aug 2020 22:07:53

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8a661454-94ae-4d02-8094-3e533d65aa6d'	System	17 Aug 2020 22:07:53
User entered 'No (N)'	System	17 Aug 2020 22:07:53

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-17T18:07:48', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8a661454-94ae-4d02-8094-3e533d65aa6d'	System	17 Aug 2020 22:07:53
User entered '17 Aug 2020 18:07'	System	17 Aug 2020 22:07:53

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 6'	System	13 Aug 2020 17:37:22

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:16', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b580476d-08ab-4618-8875-6d731bbdca30'	System	19 Aug 2020 15:01:34
User entered 'None (0)'	System	19 Aug 2020 15:01:34



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:18', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b580476d-08ab-4618-8875-6d731bbdca30'	System	19 Aug 2020 15:01:34
User entered 'None (0)'	System	19 Aug 2020 15:01:34

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:19', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b580476d-08ab-4618-8875-6d731bbdca30'	System	19 Aug 2020 15:01:34
User entered 'None (0)'	System	19 Aug 2020 15:01:34

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:21', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b580476d-08ab-4618-8875-6d731bbdca30'	System	19 Aug 2020 15:01:34
User entered 'None (0)'	System	19 Aug 2020 15:01:34

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:23', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b580476d-08ab-4618-8875-6d731bbdca30'	System	19 Aug 2020 15:01:34
User entered 'None (0)'	System	19 Aug 2020 15:01:34

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:25', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b580476d-08ab-4618-8875-6d731bbdca30'	System	19 Aug 2020 15:01:34
User entered 'None (0)'	System	19 Aug 2020 15:01:34

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:28', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b580476d-08ab-4618-8875-6d731bbdca30'	System	19 Aug 2020 15:01:34
User entered 'No (N)'	System	19 Aug 2020 15:01:34

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-19T11:01:33', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b580476d-08ab-4618-8875-6d731bbdca30'	System	19 Aug 2020 15:01:34
User entered '19 Aug 2020 11:01'	System	19 Aug 2020 15:01:34

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:37:22



**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 7'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:35', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0a932e5c-5c42-4683-8d28-4fbd2cc87404'	System	20 Aug 2020 15:19:54
User entered 'None (0)'	System	20 Aug 2020 15:19:54

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:37', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0a932e5c-5c42-4683-8d28-4fbd2cc87404'	System	20 Aug 2020 15:19:54
User entered 'None (0)'	System	20 Aug 2020 15:19:54

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:39', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0a932e5c-5c42-4683-8d28-4fbd2cc87404'	System	20 Aug 2020 15:19:54
User entered 'None (0)'	System	20 Aug 2020 15:19:54

US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:41', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0a932e5c-5c42-4683-8d28-4fbd2cc87404'	System	20 Aug 2020 15:19:54
User entered 'None (0)'	System	20 Aug 2020 15:19:54

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:43', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0a932e5c-5c42-4683-8d28-4fbd2cc87404'	System	20 Aug 2020 15:19:54
User entered 'None (0)'	System	20 Aug 2020 15:19:54

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0a932e5c-5c42-4683-8d28-4fbd2cc87404'	System	20 Aug 2020 15:19:54
User entered 'None (0)'	System	20 Aug 2020 15:19:54



US3152162

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:48', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0a932e5c-5c42-4683-8d28-4fbd2cc87404'	System	20 Aug 2020 15:19:54
User entered 'No (N)'	System	20 Aug 2020 15:19:54

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-08-20T11:19:51', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0a932e5c-5c42-4683-8d28-4fbd2cc87404'	System	20 Aug 2020 15:19:54
User entered '20 Aug 2020 11:19'	System	20 Aug 2020 15:19:54

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:37:22

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	21 Aug 2020 13:51:56

**US3152162**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '20 Aug 2020'	Juliana DeVito (b) (4)	21 Aug 2020 13:51:56

**US3152162**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Contact Made (CONTACT MADE)'	Juliana DeVito (b) (4)	21 Aug 2020 13:51:56

US3152162

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Juliana DeVito (b) (4)	21 Aug 2020 13:51:56
	(b) (4)	



**US3152162**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	21 Aug 2020 13:52:00

**US3152162**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'I'	System	21 Aug 2020 13:52:00

**US3152162**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	10 Sep 2020 20:46:29

**US3152162**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '28 Aug 2020'	Jemario Blackwell (b) (4)	10 Sep 2020 20:46:29

**US3152162**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	10 Sep 2020 20:46:29

US3152162

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Jemario Blackwell (b) (4) (b) (4)	10 Sep 2020 20:46:29

**US3152162**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	10 Sep 2020 20:46:34

**US3152162**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'I'	System	10 Sep 2020 20:46:34



**US3152162**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	10 Sep 2020 20:46:55

**US3152162**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '3 Sep 2020'	Jemario Blackwell (b) (4)	10 Sep 2020 20:46:55

**US3152162**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	10 Sep 2020 20:46:55

**US3152162**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Jemario Blackwell (b) (4) (b) (4)	10 Sep 2020 20:46:55

**US3152162**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	10 Sep 2020 20:47:02

**US3152162**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'I'	System	10 Sep 2020 20:47:02

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:01:34

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:01:34



**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Sep 2020 14:01:34

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'VISIT2'	System	14 Sep 2020 14:01:34

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User accepted default value 'Pre-Dose (PREDOSE)'		14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '15:25'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '10 Sep 2020 15:25'	System	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '37.1' C	(b) (4), (b) (6)	14 Sep 2020 14:03:46



**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '87'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'bpm'	System	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '16'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

US3152162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'breaths/min'	System	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '137'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	14 Sep 2020 14:03:46



**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '85'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User accepted default value 'Post-Dose (POSTDOSE)'		14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '17:03'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '10 Sep 2020 17:03'	System	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '36.7' C	(b) (4), (b) (6)	14 Sep 2020 14:03:46



**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '83'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'bpm'	System	14 Sep 2020 14:03:46

US3152162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '14'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

US3152162

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'breaths/min'	System	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '131'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	14 Sep 2020 14:03:46



**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '85'	(b) (4), (b) (6)	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	14 Sep 2020 14:03:46

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:27:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:03:59

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:27:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:03:59

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 14:04:16

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:04:16

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:04:16

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:04:16



**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:04:16

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:04:16

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:04:16

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered empty.	System	14 Sep 2020 14:04:16

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:55**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	10 Sep 2020 20:47:39

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:55**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Jemario Blackwell (b) (4)	10 Sep 2020 20:47:39

US3152162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

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)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Jemario Blackwell (b) (4)	10 Sep 2020 20:47:39

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:55**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 20:47:39



US3152162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '10 Sep 2020'	Jemario Blackwell (b) (4)	10 Sep 2020 20:47:39

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '16:33'	Jemario Blackwell (b) (4)	10 Sep 2020 20:47:39

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '10 Sep 2020 16:33'	System	10 Sep 2020 20:47:39

US3152162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Left Arm (LEFT ARM)'	Jemario Blackwell (b) (4)	10 Sep 2020 20:47:39

US3152162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'ONCE'	System	10 Sep 2020 20:47:39

US3152162

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:55

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:08:37

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:08:37



**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '15:37'	(b) (4), (b) (6)	14 Sep 2020 14:08:37

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '10 Sep 2020 15:37'	System	14 Sep 2020 14:08:37

US3152162

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 14:09:04

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Sep 2020 14:09:04

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:09:04

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '15:50'	(b) (4), (b) (6)	14 Sep 2020 14:09:04

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '10 Sep 2020 15:50'	System	14 Sep 2020 14:09:04

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Sep 2020 14:09:04



**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 14:09:04

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:09:04

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered empty.	System	14 Sep 2020 14:09:04

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:09:13

**US3152162**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'I'	System	14 Sep 2020 14:09:13

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:06:25', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'febbd27d-70be-4fac-97ef-103f9cb473aa'	System	10 Sep 2020 21:06:41
User entered 'Yes (Y)'	System	10 Sep 2020 21:06:41

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:06:30', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'febbd27d-70be-4fac-97ef-103f9cb473aa'	System	10 Sep 2020 21:06:41
User entered '98.0'	System	10 Sep 2020 21:06:41



US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:06:33', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'febbd27d-70be-4fac-97ef-103f9cb473aa'	System	10 Sep 2020 21:06:41
User entered 'No (N)'	System	10 Sep 2020 21:06:41

**US3152162**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:06:37', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'febbd27d-70be-4fac-97ef-103f9cb473aa'	System	10 Sep 2020 21:06:41
User entered '10 Sep 2020 17:06'	System	10 Sep 2020 21:06:41

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '10 Sep 2020 16:53'	System	10 Sep 2020 20:47:39

**US3152162**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '10 Sep 2020 19:23'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:09:33', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2d8d9e9f-9a41-4bee-a70f-e91cb9a3f39a'	System	11 Sep 2020 14:10:14
User entered 'Yes (Y)'	System	11 Sep 2020 14:10:14

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:09:39', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2d8d9e9f-9a41-4bee-a70f-e91cb9a3f39a'	System	11 Sep 2020 14:10:14
User entered '98.6'	System	11 Sep 2020 14:10:14

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:09:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2d8d9e9f-9a41-4bee-a70f-e91cb9a3f39a'	System	11 Sep 2020 14:10:14
User entered 'No (N)'	System	11 Sep 2020 14:10:14



**US3152162**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:10:07', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2d8d9e9f-9a41-4bee-a70f-e91cb9a3f39a'	System	11 Sep 2020 14:10:14
User entered '11 Sep 2020 10:10'	System	11 Sep 2020 14:10:14

**US3152162**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '10 Sep 2020 20:18'	System	10 Sep 2020 20:47:39

**US3152162**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 2'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:55:19', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0943a391-3f44-4363-b254-9e9ddb46b202'	System	11 Sep 2020 22:56:11
User entered 'Yes (Y)'	System	11 Sep 2020 22:56:11

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:55:25', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0943a391-3f44-4363-b254-9e9ddb46b202'	System	11 Sep 2020 22:56:11
User entered '98.4'	System	11 Sep 2020 22:56:11

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:55:52', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0943a391-3f44-4363-b254-9e9ddb46b202'	System	11 Sep 2020 22:56:11
User entered 'No (N)'	System	11 Sep 2020 22:56:11

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:56:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0943a391-3f44-4363-b254-9e9ddb46b202'	System	11 Sep 2020 22:56:11
User entered '11 Sep 2020 18:56'	System	11 Sep 2020 22:56:11



**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 3'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:20:39', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '95ab312d-9a1d-4a9a-8654-d6e25f0f6cee'	System	12 Sep 2020 16:20:59
User entered 'Yes (Y)'	System	12 Sep 2020 16:20:59

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:20:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '95ab312d-9a1d-4a9a-8654-d6e25f0f6cee'	System	12 Sep 2020 16:20:59
User entered '98.4'	System	12 Sep 2020 16:20:59

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:20:52', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '95ab312d-9a1d-4a9a-8654-d6e25f0f6cee'	System	12 Sep 2020 16:20:59
User entered 'No (N)'	System	12 Sep 2020 16:20:59

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:20:56', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '95ab312d-9a1d-4a9a-8654-d6e25f0f6cee'	System	12 Sep 2020 16:20:59
User entered '12 Sep 2020 12:20'	System	12 Sep 2020 16:20:59

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:47:39



US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 4'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:46:30', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd29f1f67-3554-4738-aaa2-87794268ca18'	System	13 Sep 2020 18:47:25
User entered 'Yes (Y)'	System	13 Sep 2020 18:47:25

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:46:37', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd29f1f67-3554-4738-aaa2-87794268ca18' User entered '98.7'	System	13 Sep 2020 18:47:25
	System	13 Sep 2020 18:47:25

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:46:40', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd29f1f67-3554-4738-aaa2-87794268ca18'	System	13 Sep 2020 18:47:25
User entered 'No (N)'	System	13 Sep 2020 18:47:25

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:46:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd29f1f67-3554-4738-aaa2-87794268ca18'	System	13 Sep 2020 18:47:25
User entered '13 Sep 2020 14:46'	System	13 Sep 2020 18:47:25

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:47:39



**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 5'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:06', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '07feafab-090a-4248-b7b7-324eea087d28'	System	14 Sep 2020 16:56:19
User entered 'Yes (Y)'	System	14 Sep 2020 16:56:19

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:12', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '07feafab-090a-4248-b7b7-324eea087d28'	System	14 Sep 2020 16:56:19
User entered '98.4'	System	14 Sep 2020 16:56:19

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:15', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '07feafab-090a-4248-b7b7-324eea087d28'	System	14 Sep 2020 16:56:19
User entered 'No (N)'	System	14 Sep 2020 16:56:19

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:17', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '07feafab-090a-4248-b7b7-324eea087d28'	System	14 Sep 2020 16:56:19
User entered '14 Sep 2020 12:56'	System	14 Sep 2020 16:56:19

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 6'	System	10 Sep 2020 20:47:39



US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:54:17', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4d388454-debf-4ad0-913c-95565a77b402'	System	15 Sep 2020 20:54:43
User entered 'Yes (Y)'	System	15 Sep 2020 20:54:43

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:54:35', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4d388454-debf-4ad0-913c-95565a77b402'	System	15 Sep 2020 20:54:43
User entered '98.6'	System	15 Sep 2020 20:54:43

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:54:39', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4d388454-debf-4ad0-913c-95565a77b402'	System	15 Sep 2020 20:54:43
User entered 'No (N)'	System	15 Sep 2020 20:54:43

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:54:42', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4d388454-debf-4ad0-913c-95565a77b402'	System	15 Sep 2020 20:54:43
User entered '15 Sep 2020 16:54'	System	15 Sep 2020 20:54:43

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 7'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:20:57', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2dfc8ebe-5df3-4307-afc5-1014f7182e8f'	System	16 Sep 2020 22:21:09
User entered 'Yes (Y)'	System	16 Sep 2020 22:21:09



US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:21:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2dfc8ebe-5df3-4307-afc5-1014f7182e8f' User entered '98.4'	System	16 Sep 2020 22:21:09
	System	16 Sep 2020 22:21:09

US3152162

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:21:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2dfc8ebe-5df3-4307-afc5-1014f7182e8f'	System	16 Sep 2020 22:21:09
User entered 'No (N)'	System	16 Sep 2020 22:21:09

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:21:06', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2dfc8ebe-5df3-4307-afc5-1014f7182e8f'	System	16 Sep 2020 22:21:09
User entered '16 Sep 2020 18:21'	System	16 Sep 2020 22:21:09

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

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

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

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:04:31', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '834630b5-8d44-478e-822a-04a2021aef47'	System	10 Sep 2020 21:05:10
User entered 'None (1)'	System	10 Sep 2020 21:05:10

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:04:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '834630b5-8d44-478e-822a-04a2021aef47'	System	10 Sep 2020 21:05:10
User entered 'No (N)'	System	10 Sep 2020 21:05:10



US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:04:53', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '834630b5-8d44-478e-822a-04a2021aef47'	System	10 Sep 2020 21:05:10
User entered 'No (N)'	System	10 Sep 2020 21:05:10

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:04:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '834630b5-8d44-478e-822a-04a2021aef47'	System	10 Sep 2020 21:05:10
User entered 'None (1)'	System	10 Sep 2020 21:05:10

**US3152162**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:05:04', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '834630b5-8d44-478e-822a-04a2021aef47'	System	10 Sep 2020 21:05:10
User entered '10 Sep 2020 17:05'	System	10 Sep 2020 21:05:10

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '10 Sep 2020 16:53'	System	10 Sep 2020 20:47:39

**US3152162**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '10 Sep 2020 19:23'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:12:48', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3094c681-6164-48fd-986d-f99f87a45359'	System	11 Sep 2020 14:18:41
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 14:18:41

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:12:58', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3094c681-6164-48fd-986d-f99f87a45359'	System	11 Sep 2020 14:18:41
User entered 'Yes (Y)'	System	11 Sep 2020 14:18:41



US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:16:48', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3094c681-6164-48fd-986d-f99f87a45359'	System	11 Sep 2020 14:18:41
User entered '26'	System	11 Sep 2020 14:18:41

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:16:52', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3094c681-6164-48fd-986d-f99f87a45359'	System	11 Sep 2020 14:18:41
User entered 'Yes (Y)'	System	11 Sep 2020 14:18:41

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3094c681-6164-48fd-986d-f99f87a45359'	System	11 Sep 2020 14:18:41
User entered '35'	System	11 Sep 2020 14:18:41

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:08', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3094c681-6164-48fd-986d-f99f87a45359'	System	11 Sep 2020 14:18:41
User entered 'None (1)'	System	11 Sep 2020 14:18:41

**US3152162**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:26', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3094c681-6164-48fd-986d-f99f87a45359'	System	11 Sep 2020 14:18:41
User entered '11 Sep 2020 10:17'	System	11 Sep 2020 14:18:41

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '10 Sep 2020 20:18'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 2'	System	10 Sep 2020 20:47:39



US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:56:24', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1ccc371-ef1f-482e-bdfd-79701c6c557b'	System	11 Sep 2020 22:58:30
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 22:58:30

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:56:27', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1ccc371-ef1f-482e-bdfd-79701c6c557b'	System	11 Sep 2020 22:58:30
User entered 'Yes (Y)'	System	11 Sep 2020 22:58:30

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:57:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1ccc371-ef1f-482e-bdfd-79701c6c557b'	System	11 Sep 2020 22:58:30
User entered '64'	System	11 Sep 2020 22:58:30

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:57:51', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1ccc371-ef1f-482e-bdfd-79701c6c557b'	System	11 Sep 2020 22:58:30
User entered 'Yes (Y)'	System	11 Sep 2020 22:58:30

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:57:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1ccc371-ef1f-482e-bdfd-79701c6c557b'	System	11 Sep 2020 22:58:30
User entered '64'	System	11 Sep 2020 22:58:30

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1ccc371-ef1f-482e-bdfd-79701c6c557b'	System	11 Sep 2020 22:58:30
User entered 'None (1)'	System	11 Sep 2020 22:58:30

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:12', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1ccc371-ef1f-482e-bdfd-79701c6c557b'	System	11 Sep 2020 22:58:30
User entered '11 Sep 2020 18:58'	System	11 Sep 2020 22:58:30

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:47:39



**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 3'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:21:06', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'de6da631-6439-4136-a5a1-e317f3c53cf5'	System	12 Sep 2020 16:23:18
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 16:23:18

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:21:11', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'de6da631-6439-4136-a5a1-e317f3c53cf5'	System	12 Sep 2020 16:23:18
User entered 'Yes (Y)'	System	12 Sep 2020 16:23:18

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:22:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'de6da631-6439-4136-a5a1-e317f3c53cf5'	System	12 Sep 2020 16:23:18
User entered '74'	System	12 Sep 2020 16:23:18

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:22:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'de6da631-6439-4136-a5a1-e317f3c53cf5'	System	12 Sep 2020 16:23:18
User entered 'Yes (Y)'	System	12 Sep 2020 16:23:18

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:02', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'de6da631-6439-4136-a5a1-e317f3c53cf5'	System	12 Sep 2020 16:23:18
User entered '74'	System	12 Sep 2020 16:23:18

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:05', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'de6da631-6439-4136-a5a1-e317f3c53cf5'	System	12 Sep 2020 16:23:18
User entered 'None (1)'	System	12 Sep 2020 16:23:18



**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:15', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'de6da631-6439-4136-a5a1-e317f3c53cf5'	System	12 Sep 2020 16:23:18
User entered '12 Sep 2020 12:23'	System	12 Sep 2020 16:23:18

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 4'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:46:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '063623f8-9453-4cc6-a700-d6c56355d0a6'	System	13 Sep 2020 18:47:41
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 18:47:41

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:46:52', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '063623f8-9453-4cc6-a700-d6c56355d0a6'	System	13 Sep 2020 18:47:41
User entered 'Yes (Y)'	System	13 Sep 2020 18:47:41

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:46:58', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '063623f8-9453-4cc6-a700-d6c56355d0a6'	System	13 Sep 2020 18:47:41
User entered '76'	System	13 Sep 2020 18:47:41

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:01', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '063623f8-9453-4cc6-a700-d6c56355d0a6'	System	13 Sep 2020 18:47:41
User entered 'Yes (Y)'	System	13 Sep 2020 18:47:41



US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:05', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '063623f8-9453-4cc6-a700-d6c56355d0a6'	System	13 Sep 2020 18:47:41
User entered '76'	System	13 Sep 2020 18:47:41

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:14', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '063623f8-9453-4cc6-a700-d6c56355d0a6'	System	13 Sep 2020 18:47:41
User entered 'None (1)'	System	13 Sep 2020 18:47:41

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:24', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '063623f8-9453-4cc6-a700-d6c56355d0a6'	System	13 Sep 2020 18:47:41
User entered '13 Sep 2020 14:47'	System	13 Sep 2020 18:47:41

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 5'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:27', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0c181430-e178-4952-8893-1d3a8e14c97d'	System	14 Sep 2020 16:57:05
User entered 'None (1)'	System	14 Sep 2020 16:57:05

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:31', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0c181430-e178-4952-8893-1d3a8e14c97d'	System	14 Sep 2020 16:57:05
User entered 'Yes (Y)'	System	14 Sep 2020 16:57:05



US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:43', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0c181430-e178-4952-8893-1d3a8e14c97d'	System	14 Sep 2020 16:57:05
User entered '52'	System	14 Sep 2020 16:57:05

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0c181430-e178-4952-8893-1d3a8e14c97d'	System	14 Sep 2020 16:57:05
User entered 'Yes (Y)'	System	14 Sep 2020 16:57:05

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:55', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0c181430-e178-4952-8893-1d3a8e14c97d'	System	14 Sep 2020 16:57:05
User entered '67'	System	14 Sep 2020 16:57:05

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:56:57', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0c181430-e178-4952-8893-1d3a8e14c97d'	System	14 Sep 2020 16:57:05
User entered 'None (1)'	System	14 Sep 2020 16:57:05

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:57:01', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '0c181430-e178-4952-8893-1d3a8e14c97d'	System	14 Sep 2020 16:57:05
User entered '14 Sep 2020 12:57'	System	14 Sep 2020 16:57:05

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 6'	System	10 Sep 2020 20:47:39



US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:02', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ce825657-1730-40b7-a7ca-e5f0bd7399df'	System	15 Sep 2020 20:55:31
User entered 'None (1)'	System	15 Sep 2020 20:55:31

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:09', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ce825657-1730-40b7-a7ca-e5f0bd7399df'	System	15 Sep 2020 20:55:31
User entered 'No (N)'	System	15 Sep 2020 20:55:31

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:16', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ce825657-1730-40b7-a7ca-e5f0bd7399df'	System	15 Sep 2020 20:55:31
User entered 'Yes (Y)'	System	15 Sep 2020 20:55:31

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:24', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ce825657-1730-40b7-a7ca-e5f0bd7399df'	System	15 Sep 2020 20:55:31
User entered '33'	System	15 Sep 2020 20:55:31

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:27', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ce825657-1730-40b7-a7ca-e5f0bd7399df'	System	15 Sep 2020 20:55:31
User entered 'None (1)'	System	15 Sep 2020 20:55:31

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:29', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ce825657-1730-40b7-a7ca-e5f0bd7399df'	System	15 Sep 2020 20:55:31
User entered '15 Sep 2020 16:55'	System	15 Sep 2020 20:55:31

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:47:39



US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 7'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:21:15', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c65e5174-0e2e-4f7f-915a-4dac7db75166'	System	16 Sep 2020 22:22:39
User entered 'None (1)'	System	16 Sep 2020 22:22:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:21:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c65e5174-0e2e-4f7f-915a-4dac7db75166'	System	16 Sep 2020 22:22:39
User entered 'No (N)'	System	16 Sep 2020 22:22:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:12', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c65e5174-0e2e-4f7f-915a-4dac7db75166'	System	16 Sep 2020 22:22:39
User entered 'Yes (Y)'	System	16 Sep 2020 22:22:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:26', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c65e5174-0e2e-4f7f-915a-4dac7db75166'	System	16 Sep 2020 22:22:39
User entered '26'	System	16 Sep 2020 22:22:39

US3152162

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:33', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c65e5174-0e2e-4f7f-915a-4dac7db75166'	System	16 Sep 2020 22:22:39
User entered 'None (1)'	System	16 Sep 2020 22:22:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:39', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c65e5174-0e2e-4f7f-915a-4dac7db75166'	System	16 Sep 2020 22:22:39
User entered '16 Sep 2020 18:22'	System	16 Sep 2020 22:22:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:47:39



**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:05:22', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7e7613c8-b337-4631-8703-dd0c8ec0251e'	System	10 Sep 2020 21:05:50
User entered 'None (0)'	System	10 Sep 2020 21:05:50

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:05:26', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7e7613c8-b337-4631-8703-dd0c8ec0251e'	System	10 Sep 2020 21:05:50
User entered 'None (0)'	System	10 Sep 2020 21:05:50

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:05:29', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7e7613c8-b337-4631-8703-dd0c8ec0251e'	System	10 Sep 2020 21:05:50
User entered 'None (0)'	System	10 Sep 2020 21:05:50

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:05:32', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7e7613c8-b337-4631-8703-dd0c8ec0251e' User entered 'None (0)'	System	10 Sep 2020 21:05:50
	System	10 Sep 2020 21:05:50

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:05:34', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7e7613c8-b337-4631-8703-dd0c8ec0251e'	System	10 Sep 2020 21:05:50
User entered 'None (0)'	System	10 Sep 2020 21:05:50

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:05:37', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7e7613c8-b337-4631-8703-dd0c8ec0251e'	System	10 Sep 2020 21:05:50
User entered 'None (0)'	System	10 Sep 2020 21:05:50



US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:05:42', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7e7613c8-b337-4631-8703-dd0c8ec0251e'	System	10 Sep 2020 21:05:50
User entered 'No (N)'	System	10 Sep 2020 21:05:50

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-10T17:05:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7e7613c8-b337-4631-8703-dd0c8ec0251e' User entered '10 Sep 2020 17:05'	System	10 Sep 2020 21:05:50
	System	10 Sep 2020 21:05:50

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '10 Sep 2020 16:53'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '10 Sep 2020 19:23'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:34', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cf7b5ad8-3b36-48be-966e-c4e0b4d6c149'	System	11 Sep 2020 22:29:11
User entered 'None (0)'	System	11 Sep 2020 22:29:11

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:44', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cf7b5ad8-3b36-48be-966e-c4e0b4d6c149'	System	11 Sep 2020 22:29:11
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:29:11

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:48', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cf7b5ad8-3b36-48be-966e-c4e0b4d6c149'	System	11 Sep 2020 22:29:11
User entered 'None (0)'	System	11 Sep 2020 22:29:11



US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cf7b5ad8-3b36-48be-966e-c4e0b4d6c149'	System	11 Sep 2020 22:29:11
User entered 'None (0)'	System	11 Sep 2020 22:29:11

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:53', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cf7b5ad8-3b36-48be-966e-c4e0b4d6c149'	System	11 Sep 2020 22:29:11
User entered 'None (0)'	System	11 Sep 2020 22:29:11

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:56', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cf7b5ad8-3b36-48be-966e-c4e0b4d6c149'	System	11 Sep 2020 22:29:11
User entered 'None (0)'	System	11 Sep 2020 22:29:11

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:17:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cf7b5ad8-3b36-48be-966e-c4e0b4d6c149'	System	11 Sep 2020 22:29:11
User entered 'No (N)'	System	11 Sep 2020 22:29:11

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T10:18:04', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cf7b5ad8-3b36-48be-966e-c4e0b4d6c149'	System	11 Sep 2020 22:29:11
User entered '11 Sep 2020 10:18'	System	11 Sep 2020 22:29:11

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '10 Sep 2020 20:18'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 2'	System	10 Sep 2020 20:47:39



US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:17', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4397c00f-9870-4b7a-b3f4-b3d09150af28'	System	11 Sep 2020 22:59:06
User entered 'None (0)'	System	11 Sep 2020 22:59:06

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:21', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4397c00f-9870-4b7a-b3f4-b3d09150af28'	System	11 Sep 2020 22:59:06
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:59:06

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:26', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4397c00f-9870-4b7a-b3f4-b3d09150af28'	System	11 Sep 2020 22:59:06
User entered 'None (0)'	System	11 Sep 2020 22:59:06

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:30', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4397c00f-9870-4b7a-b3f4-b3d09150af28'	System	11 Sep 2020 22:59:06
User entered 'None (0)'	System	11 Sep 2020 22:59:06

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:32', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4397c00f-9870-4b7a-b3f4-b3d09150af28'	System	11 Sep 2020 22:59:06
User entered 'None (0)'	System	11 Sep 2020 22:59:06

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:35', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4397c00f-9870-4b7a-b3f4-b3d09150af28'	System	11 Sep 2020 22:59:06
User entered 'None (0)'	System	11 Sep 2020 22:59:06

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:41', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4397c00f-9870-4b7a-b3f4-b3d09150af28'	System	11 Sep 2020 22:59:06
User entered 'No (N)'	System	11 Sep 2020 22:59:06

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-11T18:58:48', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '4397c00f-9870-4b7a-b3f4-b3d09150af28'	System	11 Sep 2020 22:59:06
User entered '11 Sep 2020 18:58'	System	11 Sep 2020 22:59:06



**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 3'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:20', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ae558d1a-c1c8-4a65-93ca-23db81b85e59'	System	12 Sep 2020 16:23:50
User entered 'None (0)'	System	12 Sep 2020 16:23:50

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:23', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ae558d1a-c1c8-4a65-93ca-23db81b85e59'	System	12 Sep 2020 16:23:50
User entered 'No interference with activity (1)'	System	12 Sep 2020 16:23:50

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:30', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ae558d1a-c1c8-4a65-93ca-23db81b85e59'	System	12 Sep 2020 16:23:50
User entered 'None (0)'	System	12 Sep 2020 16:23:50

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:34', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ae558d1a-c1c8-4a65-93ca-23db81b85e59'	System	12 Sep 2020 16:23:50
User entered 'None (0)'	System	12 Sep 2020 16:23:50

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:36', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ae558d1a-c1c8-4a65-93ca-23db81b85e59'	System	12 Sep 2020 16:23:50
User entered 'None (0)'	System	12 Sep 2020 16:23:50



**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:39', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ae558d1a-c1c8-4a65-93ca-23db81b85e59'	System	12 Sep 2020 16:23:50
User entered 'None (0)'	System	12 Sep 2020 16:23:50

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:43', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ae558d1a-c1c8-4a65-93ca-23db81b85e59'	System	12 Sep 2020 16:23:50
User entered 'No (N)'	System	12 Sep 2020 16:23:50

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-12T12:23:48', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ae558d1a-c1c8-4a65-93ca-23db81b85e59'	System	12 Sep 2020 16:23:50
User entered '12 Sep 2020 12:23'	System	12 Sep 2020 16:23:50

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 4'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:28', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '532e38f8-8fd8-43b5-bedd-0050c8310e3c'	System	13 Sep 2020 18:48:14
User entered 'None (0)'	System	13 Sep 2020 18:48:14

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:31', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '532e38f8-8fd8-43b5-bedd-0050c8310e3c'	System	13 Sep 2020 18:48:14
User entered 'None (0)'	System	13 Sep 2020 18:48:14



US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:40', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '532e38f8-8fd8-43b5-bedd-0050c8310e3c'	System	13 Sep 2020 18:48:14
User entered 'None (0)'	System	13 Sep 2020 18:48:14

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:44', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '532e38f8-8fd8-43b5-bedd-0050c8310e3c'	System	13 Sep 2020 18:48:14
User entered 'None (0)'	System	13 Sep 2020 18:48:14

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:55**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:54', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '532e38f8-8fd8-43b5-bedd-0050c8310e3c'	System	13 Sep 2020 18:48:14
User entered 'None (0)'	System	13 Sep 2020 18:48:14

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:47:57', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '532e38f8-8fd8-43b5-bedd-0050c8310e3c'	System	13 Sep 2020 18:48:14
User entered 'None (0)'	System	13 Sep 2020 18:48:14

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:48:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '532e38f8-8fd8-43b5-bedd-0050c8310e3c'	System	13 Sep 2020 18:48:14
User entered 'No (N)'	System	13 Sep 2020 18:48:14

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-13T14:48:02', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '532e38f8-8fd8-43b5-bedd-0050c8310e3c'	System	13 Sep 2020 18:48:14
User entered '13 Sep 2020 14:48'	System	13 Sep 2020 18:48:14

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:47:39



**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 5'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:57:04', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '59739c5e-471b-4007-a6c8-bea4d04fa91c'	System	14 Sep 2020 16:57:23
User entered 'None (0)'	System	14 Sep 2020 16:57:23

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:57:06', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '59739c5e-471b-4007-a6c8-bea4d04fa91c'	System	14 Sep 2020 16:57:23
User entered 'None (0)'	System	14 Sep 2020 16:57:23

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:57:08', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '59739c5e-471b-4007-a6c8-bea4d04fa91c'	System	14 Sep 2020 16:57:23
User entered 'None (0)'	System	14 Sep 2020 16:57:23

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:57:10', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '59739c5e-471b-4007-a6c8-bea4d04fa91c'	System	14 Sep 2020 16:57:23
User entered 'None (0)'	System	14 Sep 2020 16:57:23

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:57:12', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '59739c5e-471b-4007-a6c8-bea4d04fa91c'	System	14 Sep 2020 16:57:23
User entered 'None (0)'	System	14 Sep 2020 16:57:23

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:57:14', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '59739c5e-471b-4007-a6c8-bea4d04fa91c'	System	14 Sep 2020 16:57:23
User entered 'None (0)'	System	14 Sep 2020 16:57:23

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:57:17', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '59739c5e-471b-4007-a6c8-bea4d04fa91c'	System	14 Sep 2020 16:57:23
User entered 'No (N)'	System	14 Sep 2020 16:57:23



**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-14T12:57:20', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '59739c5e-471b-4007-a6c8-bea4d04fa91c'	System	14 Sep 2020 16:57:23
User entered '14 Sep 2020 12:57'	System	14 Sep 2020 16:57:23

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 6'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:33', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'e9f3b950-2b59-41a4-8b12-d20e58f16a4e'	System	15 Sep 2020 20:55:51
User entered 'None (0)'	System	15 Sep 2020 20:55:51

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:35', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'e9f3b950-2b59-41a4-8b12-d20e58f16a4e'	System	15 Sep 2020 20:55:51
User entered 'None (0)'	System	15 Sep 2020 20:55:51

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:37', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'e9f3b950-2b59-41a4-8b12-d20e58f16a4e'	System	15 Sep 2020 20:55:51
User entered 'None (0)'	System	15 Sep 2020 20:55:51

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:40', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'e9f3b950-2b59-41a4-8b12-d20e58f16a4e'	System	15 Sep 2020 20:55:51
User entered 'None (0)'	System	15 Sep 2020 20:55:51



US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:42', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'e9f3b950-2b59-41a4-8b12-d20e58f16a4e'	System	15 Sep 2020 20:55:51
User entered 'None (0)'	System	15 Sep 2020 20:55:51

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'e9f3b950-2b59-41a4-8b12-d20e58f16a4e'	System	15 Sep 2020 20:55:51
User entered 'None (0)'	System	15 Sep 2020 20:55:51

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:48', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'e9f3b950-2b59-41a4-8b12-d20e58f16a4e'	System	15 Sep 2020 20:55:51
User entered 'No (N)'	System	15 Sep 2020 20:55:51

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-15T16:55:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'e9f3b950-2b59-41a4-8b12-d20e58f16a4e'	System	15 Sep 2020 20:55:51
User entered '15 Sep 2020 16:55'	System	15 Sep 2020 20:55:51

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	10 Sep 2020 20:47:39
User entered 'Day 7'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:43', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '46a33ea1-b24b-40e2-b567-de0850403a97'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04



US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:45', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '46a33ea1-b24b-40e2-b567-de0850403a97'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '46a33ea1-b24b-40e2-b567-de0850403a97'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:49', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '46a33ea1-b24b-40e2-b567-de0850403a97'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '46a33ea1-b24b-40e2-b567-de0850403a97'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:52', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '46a33ea1-b24b-40e2-b567-de0850403a97'	System	16 Sep 2020 22:23:04
User entered 'None (0)'	System	16 Sep 2020 22:23:04

US3152162

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:56', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '46a33ea1-b24b-40e2-b567-de0850403a97'	System	16 Sep 2020 22:23:04
User entered 'No (N)'	System	16 Sep 2020 22:23:04

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-16T18:22:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '46a33ea1-b24b-40e2-b567-de0850403a97'	System	16 Sep 2020 22:23:04
User entered '16 Sep 2020 18:22'	System	16 Sep 2020 22:23:04

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:47:39



**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:47:39

US3152162

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	15 Sep 2020 20:55:31
User entered 'Day 8'	System	15 Sep 2020 20:55:31

US3152162

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 15:27:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46

US3152162

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 20:55:31

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 20:55:31

US3152162

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(9)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	16 Sep 2020 22:22:39
User entered 'Day 9'	System	16 Sep 2020 22:22:39



US3152162

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(9)

Generated On: 09 Jun 2021 15:27:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-18T12:22:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7a518d10-c693-4a14-8e91-94a39c31d5fe'	System	18 Sep 2020 16:23:02
User entered 'No (N)'	System	18 Sep 2020 16:23:02

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(9)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-18T12:22:50', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7a518d10-c693-4a14-8e91-94a39c31d5fe'	System	18 Sep 2020 16:23:02
User entered '18 Sep 2020 12:22'	System	18 Sep 2020 16:23:02

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(9)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:22:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(9)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:22:39

US3152162

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	15 Sep 2020 20:55:31
User entered 'Day 8'	System	15 Sep 2020 20:55:31

US3152162

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 20:55:31



**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 20:55:31

US3152162

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:27:55

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	16 Sep 2020 22:22:39
User entered 'Day 9'	System	16 Sep 2020 22:22:39

US3152162

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:27:55

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 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-18T12:22:58', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd75c7de6-8364-4745-84f5-f05e4dd2fd5e'	System	18 Sep 2020 16:23:13
User entered 'No (N)'	System	18 Sep 2020 16:23:13

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-09-18T12:23:01', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd75c7de6-8364-4745-84f5-f05e4dd2fd5e'	System	18 Sep 2020 16:23:13
User entered '18 Sep 2020 12:23'	System	18 Sep 2020 16:23:13

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:22:39

**US3152162**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:27:55**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:22:39

**US3152162**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:25:41

**US3152162**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:25:41



**US3152162**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 17:25:41

**US3152162**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:25:41

**US3152162**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:25:49

**US3152162**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'I'	System	17 Sep 2020 17:25:49

**US3152162**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:08:26

**US3152162**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '24 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 21:08:26

**US3152162**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 21:08:26

US3152162

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:55

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:08:26



**US3152162**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:08:30

**US3152162**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'I'	System	01 Oct 2020 21:08:30

**US3152162**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:42:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:08:40

**US3152162**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:42:40
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 21:08:40

**US3152162**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:42:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 21:08:40

**US3152162**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:42:40
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:08:40

**US3152162**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:42:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:08:43

**US3152162**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'I'	System	01 Oct 2020 21:08:43



**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	09 Oct 2020 18:43:06

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '9 Oct 2020'	Priscilla Buahin (b) (4)	09 Oct 2020 18:43:06

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Clinic (Clinic)'	Priscilla Buahin (b) (4)	09 Oct 2020 18:43:06

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'VISIT3'	System	09 Oct 2020 18:43:06

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '9 Oct 2020'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '14:11'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '9 Oct 2020 14:11'	System	09 Oct 2020 18:44:12



US3152162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '37.3' C	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Oral (Oral)'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '83'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'bpm'	System	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '14'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12

US3152162

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'breaths/min'	System	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '129'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12



**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '87'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'mmHg'	System	09 Oct 2020 18:44:12

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:27:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'No (N)'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:26

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:27:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered empty.	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:26

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:49



**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '9 Oct 2020'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:49

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered '14:19'	Priscilla Buahin (b) (4)	09 Oct 2020 18:44:49

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered '9 Oct 2020 14:19'	System	09 Oct 2020 18:44:49

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:10:58
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	09 Oct 2020 18:45:46

**US3152162**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'I'	System	09 Oct 2020 18:45:46

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 64'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-10-16T13:56:10', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ddc6a2c3-367d-437a-9560-4e64ee1be404'	System	16 Oct 2020 17:56:24
User entered 'No (N)'	System	16 Oct 2020 17:56:24

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-10-16T13:56:16', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ddc6a2c3-367d-437a-9560-4e64ee1be404'	System	16 Oct 2020 17:56:24
User entered 'No (N)'	System	16 Oct 2020 17:56:24



**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-10-16T13:56:20', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ddc6a2c3-367d-437a-9560-4e64ee1be404'	System	16 Oct 2020 17:56:24
User entered '16 Oct 2020 13:56:20'	System	16 Oct 2020 17:56:24

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 71'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-10-21T13:24:09', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '01225c30-1c68-4efa-929a-a34c40e0045d'	System	21 Oct 2020 17:24:25
User entered 'No (N)'	System	21 Oct 2020 17:24:25

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-10-21T13:24:18', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '01225c30-1c68-4efa-929a-a34c40e0045d'	System	21 Oct 2020 17:24:25
User entered 'No (N)'	System	21 Oct 2020 17:24:25

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-10-21T13:24:21', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '01225c30-1c68-4efa-929a-a34c40e0045d'	System	21 Oct 2020 17:24:25
User entered '21 Oct 2020 13:24:21'	System	21 Oct 2020 17:24:25

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 17:37:22



**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 78'	System	13 Aug 2020 17:37:22

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-10-28T00:01:27', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3d27f726-3a56-46fe-9d2e-cc16f981995b'	System	28 Oct 2020 04:01:51
User entered 'No (N)'	System	28 Oct 2020 04:01:51

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-10-28T00:01:44', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3d27f726-3a56-46fe-9d2e-cc16f981995b'	System	28 Oct 2020 04:01:51
User entered 'No (N)'	System	28 Oct 2020 04:01:51

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-10-28T00:01:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '3d27f726-3a56-46fe-9d2e-cc16f981995b' User entered '28 Oct 2020 00:01:47'	System	28 Oct 2020 04:01:51
	System	28 Oct 2020 04:01:51

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 92'	System	13 Aug 2020 17:37:22



US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-11T16:21:20', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a53f5e58-eef7-47ec-9db2-0c9de88925e1'	System	11 Nov 2020 21:22:27
User entered 'No (N)'	System	11 Nov 2020 21:22:27

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-11T16:21:36', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a53f5e58-eef7-47ec-9db2-0c9de88925e1'	System	11 Nov 2020 21:22:27
User entered 'No (N)'	System	11 Nov 2020 21:22:27

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-11T16:22:25', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a53f5e58-eef7-47ec-9db2-0c9de88925e1'	System	11 Nov 2020 21:22:27
User entered '11 Nov 2020 16:22:25'	System	11 Nov 2020 21:22:27

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered 'Day 99'	System	13 Aug 2020 17:37:22

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		29 Dec 2020 04:30:47
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Multiple unsuccessful attempts were made to contact subject to follow up on this diary entry. Subject did not respond.' (Site from DM).	Priscilla Buahin (b) (4) (b) (4)	23 Dec 2020 20:51:01
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:08:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-17T11:50:06', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b5ff6fa7-e25f-4896-b792-dc90d081c827'	System	17 Nov 2020 16:51:57
User entered 'Yes (Y)'	System	17 Nov 2020 16:51:57

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-17T11:50:09', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b5ff6fa7-e25f-4896-b792-dc90d081c827'	System	17 Nov 2020 16:51:57
User entered 'No (N)'	System	17 Nov 2020 16:51:57



**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-17T11:50:12', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b5ff6fa7-e25f-4896-b792-dc90d081c827'	System	17 Nov 2020 16:51:57
User entered 'No (N)'	System	17 Nov 2020 16:51:57

US3152162

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:55

[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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-17T11:50:39', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b5ff6fa7-e25f-4896-b792-dc90d081c827'	System	17 Nov 2020 16:51:57
User entered 'Yes (Y)'	System	17 Nov 2020 16:51:57

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-17T11:50:49', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b5ff6fa7-e25f-4896-b792-dc90d081c827'	System	17 Nov 2020 16:51:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 16:51:57

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-17T11:51:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'b5ff6fa7-e25f-4896-b792-dc90d081c827'	System	17 Nov 2020 16:51:57
User entered '17 Nov 2020 11:51:47'	System	17 Nov 2020 16:51:57

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:07:46
Data entry locked.	System	13 Aug 2020 17:37:22
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 17:37:22

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (8898a18d18ba0101)', Time: '2020-11-21T00:14:03', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cee1ae20-2aac-4b24-8883-b138f12a42f0'	System	21 Nov 2020 05:14:13
User entered 'No (N)'	System	21 Nov 2020 05:14:13



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (8898a18d18ba0101)', Time: '2020-11-21T00:14:05', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cee1ae20-2aac-4b24-8883-b138f12a42f0'	System	21 Nov 2020 05:14:13
User entered 'No (N)'	System	21 Nov 2020 05:14:13

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-11-21T00:14:09', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'cee1ae20-2aac-4b24-8883-b138f12a42f0'	System	21 Nov 2020 05:14:13
User entered '21 Nov 2020 00:14:09'	System	21 Nov 2020 05:14:13

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (8898a18d18ba0101)', Time: '2020-12-08T13:25:43', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1bedd4a4-ca07-4322-ab45-98f8c3c98240'	System	08 Dec 2020 18:25:54
User entered 'No (N)'	System	08 Dec 2020 18:25:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (8898a18d18ba0101)', Time: '2020-12-08T13:25:46', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1bedd4a4-ca07-4322-ab45-98f8c3c98240'	System	08 Dec 2020 18:25:54
User entered 'No (N)'	System	08 Dec 2020 18:25:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-12-08T13:25:51', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1bedd4a4-ca07-4322-ab45-98f8c3c98240'	System	08 Dec 2020 18:25:54
User entered '08 Dec 2020 13:25:51'	System	08 Dec 2020 18:25:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (8898a18d18ba0101)', Time: '2020-12-12T00:36:37', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '51e488e4-8b80-4e6a-864c-e1ad7daa4276'	System	12 Dec 2020 05:43:17
User entered 'No (N)'	System	12 Dec 2020 05:43:17

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (8898a18d18ba0101)', Time: '2020-12-12T00:36:49', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '51e488e4-8b80-4e6a-864c-e1ad7daa4276'	System	12 Dec 2020 05:43:17
User entered 'No (N)'	System	12 Dec 2020 05:43:17



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-12-12T00:36:57', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '51e488e4-8b80-4e6a-864c-e1ad7daa4276' User entered '12 Dec 2020 00:36:57'	System	12 Dec 2020 05:43:17
	System	12 Dec 2020 05:43:17

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (8898a18d18ba0101)', Time: '2020-12-21T10:40:41', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2b0fed8a-31ef-4b8c-9bcc-9f68018abdd'	System	21 Dec 2020 15:40:54
User entered 'No (N)'	System	21 Dec 2020 15:40:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (8898a18d18ba0101)', Time: '2020-12-21T10:40:47', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2b0fed8a-31ef-4b8c-9bcc-9f68018abdd'	System	21 Dec 2020 15:40:54
User entered 'No (N)'	System	21 Dec 2020 15:40:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-12-21T10:40:51', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2b0fed8a-31ef-4b8c-9bcc-9f68018abdd'	System	21 Dec 2020 15:40:54
User entered '21 Dec 2020 10:40:51'	System	21 Dec 2020 15:40:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (8898a18d18ba0101)', Time: '2020-12-27T21:05:35', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '81e7f420-8578-4b7e-b409-67c39e2b4fab'	System	28 Dec 2020 02:05:46
User entered 'No (N)'	System	28 Dec 2020 02:05:46

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (8898a18d18ba0101)', Time: '2020-12-27T21:05:39', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '81e7f420-8578-4b7e-b409-67c39e2b4fab'	System	28 Dec 2020 02:05:46
User entered 'No (N)'	System	28 Dec 2020 02:05:46

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2020-12-27T21:05:41', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '81e7f420-8578-4b7e-b409-67c39e2b4fab' User entered '27 Dec 2020 21:05:41'	System	28 Dec 2020 02:05:46

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (8898a18d18ba0101)', Time: '2021-01-02T00:08:23', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8d2da535-2351-447b-a4ef-dc1b24fa20e2'	System	02 Jan 2021 05:08:43
User entered 'No (N)'	System	02 Jan 2021 05:08:43

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (8898a18d18ba0101)', Time: '2021-01-02T00:08:38', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8d2da535-2351-447b-a4ef-dc1b24fa20e2'	System	02 Jan 2021 05:08:43
User entered 'No (N)'	System	02 Jan 2021 05:08:43

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2021-01-02T00:08:41', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8d2da535-2351-447b-a4ef-dc1b24fa20e2'	System	02 Jan 2021 05:08:43
User entered '02 Jan 2021 00:08:41'	System	02 Jan 2021 05:08:43

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (8898a18d18ba0101)', Time: '2021-01-10T07:52:53', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd58ce839-6ee3-4015-aaef-88b5ac406621'	System	10 Jan 2021 12:53:09
User entered 'No (N)'	System	10 Jan 2021 12:53:09

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (8898a18d18ba0101)', Time: '2021-01-10T07:53:01', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd58ce839-6ee3-4015-aaef-88b5ac406621'	System	10 Jan 2021 12:53:09
User entered 'No (N)'	System	10 Jan 2021 12:53:09



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2021-01-10T07:53:05', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'd58ce839-6ee3-4015-aaef-88b5ac406621'	System	10 Jan 2021 12:53:09
User entered '10 Jan 2021 07:53:05'	System	10 Jan 2021 12:53:09

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (8898a18d18ba0101)', Time: '2021-01-17T22:06:53', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1c76d55-d6fb-42ed-abae-c2079ad6b82e'	System	18 Jan 2021 03:07:03
User entered 'No (N)'	System	18 Jan 2021 03:07:03

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (8898a18d18ba0101)', Time: '2021-01-17T22:06:56', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1c76d55-d6fb-42ed-abae-c2079ad6b82e'	System	18 Jan 2021 03:07:03
User entered 'No (N)'	System	18 Jan 2021 03:07:03

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8898a18d18ba0101)', Time: '2021-01-17T22:06:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'a1c76d55-d6fb-42ed-abae-c2079ad6b82e' User entered '17 Jan 2021 22:06:59'	System	18 Jan 2021 03:07:03

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-01-27T12:26:53', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '5ff3521e-5790-41fd-b6af-b857b16f5bfc'	System	27 Jan 2021 17:27:05
User entered 'No (N)'	System	27 Jan 2021 17:27:05

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-01-27T12:26:59', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '5ff3521e-5790-41fd-b6af-b857b16f5bfc'	System	27 Jan 2021 17:27:05
User entered 'No (N)'	System	27 Jan 2021 17:27:05

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-01-27T12:27:01', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '5ff3521e-5790-41fd-b6af-b857b16f5bfc' User entered '27 Jan 2021 12:27:01'	System	27 Jan 2021 17:27:05

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-01-30T01:01:48', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '326696fb-a5e0-4727-bd37-2dfcd0fd4db6'	System	30 Jan 2021 06:02:45
User entered 'No (N)'	System	30 Jan 2021 06:02:45

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-01-30T01:02:06', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '326696fb-a5e0-4727-bd37-2dfcd0fd4db6'	System	30 Jan 2021 06:02:45
User entered 'No (N)'	System	30 Jan 2021 06:02:45

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-01-30T01:02:14', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '326696fb-a5e0-4727-bd37-2dfcd0fd4db6' User entered '30 Jan 2021 01:02:14'	System	30 Jan 2021 06:02:45
	System	30 Jan 2021 06:02:45

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-02-06T08:14:22', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7ff2205d-9da1-489f-ba82-a7246859280e'	System	06 Feb 2021 13:14:33
User entered 'No (N)'	System	06 Feb 2021 13:14:33

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-02-06T08:14:28', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7ff2205d-9da1-489f-ba82-a7246859280e'	System	06 Feb 2021 13:14:33
User entered 'No (N)'	System	06 Feb 2021 13:14:33



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-02-06T08:14:31', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '7ff2205d-9da1-489f-ba82-a7246859280e'	System	06 Feb 2021 13:14:33
User entered '06 Feb 2021 08:14:31'	System	06 Feb 2021 13:14:33

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-02-13T10:31:20', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '41399ce4-dd99-430d-90e2-af9b709ea944'	System	13 Feb 2021 15:31:32
User entered 'No (N)'	System	13 Feb 2021 15:31:32

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-02-13T10:31:24', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '41399ce4-dd99-430d-90e2-af9b709ea944'	System	13 Feb 2021 15:31:32
User entered 'No (N)'	System	13 Feb 2021 15:31:32

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-02-13T10:31:26', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '41399ce4-dd99-430d-90e2-af9b709ea944'	System	13 Feb 2021 15:31:32
User entered '13 Feb 2021 10:31:26'	System	13 Feb 2021 15:31:32

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-02-24T09:50:49', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '612c9ae9-aeb0-4fc5-b79d-66f4b995c2d2'	System	24 Feb 2021 14:51:10
User entered 'No (N)'	System	24 Feb 2021 14:51:10

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-02-24T09:50:55', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '612c9ae9-aeb0-4fc5-b79d-66f4b995c2d2'	System	24 Feb 2021 14:51:10
User entered 'No (N)'	System	24 Feb 2021 14:51:10

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-02-24T09:51:05', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '612c9ae9-aeb0-4fc5-b79d-66f4b995c2d2'	System	24 Feb 2021 14:51:10
User entered '24 Feb 2021 09:51:05'	System	24 Feb 2021 14:51:10

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-02-27T11:13:08-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8b9d4875-bab0-4315-9f15-b7b920d58137'	System	27 Feb 2021 16:13:22
User entered 'No (N)'	System	27 Feb 2021 16:13:22

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-02-27T11:13:11-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8b9d4875-bab0-4315-9f15-b7b920d58137'	System	27 Feb 2021 16:13:22
User entered 'No (N)'	System	27 Feb 2021 16:13:22

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-02-27T11:13:14-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '8b9d4875-bab0-4315-9f15-b7b920d58137'	System	27 Feb 2021 16:13:22
User entered '27 Feb 2021 11:13:14'	System	27 Feb 2021 16:13:22

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-03-06T15:36:23-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1c1164d9-9a30-441a-b827-b83eae95b50c'	System	06 Mar 2021 20:36:33
User entered 'No (N)'	System	06 Mar 2021 20:36:33

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-03-06T15:36:25-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1c1164d9-9a30-441a-b827-b83eae95b50c'	System	06 Mar 2021 20:36:33
User entered 'No (N)'	System	06 Mar 2021 20:36:33



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-03-06T15:36:29-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1c1164d9-9a30-441a-b827-b83eae95b50c' User entered '06 Mar 2021 15:36:29'	System	06 Mar 2021 20:36:33
	System	06 Mar 2021 20:36:33

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-03-13T10:24:56-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '57ae1da6-8c6d-4a9f-ae6e-c73fab80c020'	System	13 Mar 2021 15:25:09
User entered 'No (N)'	System	13 Mar 2021 15:25:09

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-03-13T10:25:01-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '57ae1da6-8c6d-4a9f-ae6e-c73fab80c020'	System	13 Mar 2021 15:25:09
User entered 'No (N)'	System	13 Mar 2021 15:25:09

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-03-13T10:25:04-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '57ae1da6-8c6d-4a9f-ae6e-c73fab80c020'	System	13 Mar 2021 15:25:09
User entered '13 Mar 2021 10:25:04'	System	13 Mar 2021 15:25:09

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-03-22T14:02:11-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '90df463b-3d6a-4e89-aaf0-9b2054d6f42e'	System	22 Mar 2021 18:02:24
User entered 'No (N)'	System	22 Mar 2021 18:02:24

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-03-22T14:02:16-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '90df463b-3d6a-4e89-aaf0-9b2054d6f42e'	System	22 Mar 2021 18:02:24
User entered 'No (N)'	System	22 Mar 2021 18:02:24

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-03-22T14:02:20-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '90df463b-3d6a-4e89-aaf0-9b2054d6f42e'	System	22 Mar 2021 18:02:24
User entered '22 Mar 2021 14:02:20'	System	22 Mar 2021 18:02:24

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-03-27T00:01:32-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'f8c189a0-462c-416e-a4a6-b8a79ad9e41c'	System	27 Mar 2021 04:05:54
User entered 'No (N)'	System	27 Mar 2021 04:05:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-03-27T00:01:37-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'f8c189a0-462c-416e-a4a6-b8a79ad9e41c'	System	27 Mar 2021 04:05:54
User entered 'No (N)'	System	27 Mar 2021 04:05:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-03-27T00:01:40-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'f8c189a0-462c-416e-a4a6-b8a79ad9e41c' User entered '27 Mar 2021 00:01:40'	System	27 Mar 2021 04:05:54
	System	27 Mar 2021 04:05:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-07T12:02:01-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1dea48ec-9161-4a10-bf30-2daea77c106f'	System	07 Apr 2021 16:09:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:09:29

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-04-07T12:02:03-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1dea48ec-9161-4a10-bf30-2daea77c106f'	System	07 Apr 2021 16:09:29
User entered 'No (N)'	System	07 Apr 2021 16:09:29



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-07T12:02:11-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1dea48ec-9161-4a10-bf30-2daea77c106f'	System	07 Apr 2021 16:09:29
User entered 'No (N)'	System	07 Apr 2021 16:09:29

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-07T12:02:14-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1dea48ec-9161-4a10-bf30-2daea77c106f'	System	07 Apr 2021 16:09:29
User entered 'Yes (Y)'	System	07 Apr 2021 16:09:29

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-04-07T12:02:18-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '1dea48ec-9161-4a10-bf30-2daea77c106f'	System	07 Apr 2021 16:09:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Apr 2021 16:09:29

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-04-07T12:02:22-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'Idea48ec-9161-4a10-bf30-2daea77c106f'	System	07 Apr 2021 16:09:29
User entered '07 Apr 2021 12:02:22'	System	07 Apr 2021 16:09:29

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-10T10:35:34-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ddce3e16-c558-43ce-a3ee-f31c068d6dbe'	System	10 Apr 2021 14:36:01
User entered 'Yes (Y)'	System	10 Apr 2021 14:36:01



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-04-10T10:35:37-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ddce3e16-c558-43ce-a3ee-f31c068d6dbe'	System	10 Apr 2021 14:36:01
User entered 'No (N)'	System	10 Apr 2021 14:36:01

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-10T10:35:40-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ddce3e16-c558-43ce-a3ee-f31c068d6dbe'	System	10 Apr 2021 14:36:01
User entered 'No (N)'	System	10 Apr 2021 14:36:01

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-10T10:35:44-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ddce3e16-c558-43ce-a3ee-f31c068d6dbe'	System	10 Apr 2021 14:36:01
User entered 'Yes (Y)'	System	10 Apr 2021 14:36:01

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-04-10T10:35:47-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ddce3e16-c558-43ce-a3ee-f31c068d6dbe'	System	10 Apr 2021 14:36:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Apr 2021 14:36:01

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-04-10T10:35:51-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'ddce3e16-c558-43ce-a3ee-f31c068d6dbe' User entered '10 Apr 2021 10:35:51'	System	10 Apr 2021 14:36:01

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-21T16:23:26-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c7d1de56-22c2-4089-b8c3-35be59375141'	System	21 Apr 2021 20:23:57
User entered 'Yes (Y)'	System	21 Apr 2021 20:23:57

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-04-21T16:23:29-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c7d1de56-22c2-4089-b8c3-35be59375141'	System	21 Apr 2021 20:23:57
User entered 'No (N)'	System	21 Apr 2021 20:23:57

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-21T16:23:33-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c7d1de56-22c2-4089-b8c3-35be59375141'	System	21 Apr 2021 20:23:57
User entered 'No (N)'	System	21 Apr 2021 20:23:57

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-21T16:23:36-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c7d1de56-22c2-4089-b8c3-35be59375141'	System	21 Apr 2021 20:23:57
User entered 'Yes (Y)'	System	21 Apr 2021 20:23:57

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-04-21T16:23:39-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c7d1de56-22c2-4089-b8c3-35be59375141'	System	21 Apr 2021 20:23:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Apr 2021 20:23:57

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-04-21T16:23:42-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: 'c7d1de56-22c2-4089-b8c3-35be59375141'	System	21 Apr 2021 20:23:57
User entered '21 Apr 2021 16:23:42'	System	21 Apr 2021 20:23:57

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-04-25T15:10:44-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '9be3e82c-a731-4bde-a56a-a2a4caa813ed' User entered 'No (N)'	System	25 Apr 2021 19:10:53
	System	25 Apr 2021 19:10:53

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-04-25T15:10:47-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '9be3e82c-a731-4bde-a56a-a2a4caa813ed' User entered 'No (N)'	System	25 Apr 2021 19:10:53

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-04-25T15:10:50-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '9be3e82c-a731-4bde-a56a-a2a4caa813ed' User entered '25 Apr 2021 15:10:50'	System	25 Apr 2021 19:10:53
	System	25 Apr 2021 19:10:53

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[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 (c40a80871b544f44)', Time: '2021-05-03T00:26:45-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '201b12ea-12c5-4676-abd4-b42a8db42aa8'	System	03 May 2021 04:26:54
User entered 'No (N)'	System	03 May 2021 04:26:54



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

Have you been exposed to someone with 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 (c40a80871b544f44)', Time: '2021-05-03T00:26:49-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '201b12ea-12c5-4676-abd4-b42a8db42aa8'	System	03 May 2021 04:26:54
User entered 'No (N)'	System	03 May 2021 04:26:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-05-03T00:26:52-04:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '201b12ea-12c5-4676-abd4-b42a8db42aa8'	System	03 May 2021 04:26:54
User entered '03 May 2021 00:26:52'	System	03 May 2021 04:26:54

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:05:02



**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:05:02

**US3152162**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:55**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:05:02
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:05:02



US3152162

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:27:55

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 15:34:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-02-27T11:13:59-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2051baa7-544b-4b9b-a22d-1e76e6692b65'	System	27 Feb 2021 16:14:08
User entered 'No (N)'	System	27 Feb 2021 16:14:08

**US3152162**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:34:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c40a80871b544f44)', Time: '2021-02-27T11:14:03-05:00', User OID: 'PatientReportedOutcome (US3152162)', ODM File OID: '2051baa7-544b-4b9b-a22d-1e76e6692b65'	System	27 Feb 2021 16:14:08
User entered '27 Feb 2021 11:14:03'	System	27 Feb 2021 16:14:08

**US3152162**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:00
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	02 Nov 2020 16:51:18

**US3152162**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:00
User entered '2 Nov 2020'	Tanya Alexander (b) (4)	02 Nov 2020 16:51:18

**US3152162**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:00
User entered 'Contact Made (CONTACT MADE)'	Tanya Alexander (b) (4)	02 Nov 2020 16:51:18

**US3152162**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:00
User entered empty.	Tanya Alexander (b) (4)	02 Nov 2020 16:51:18

**US3152162**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:55:00
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	02 Nov 2020 16:51:24

**US3152162**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:05:32
User entered 'I'	System	02 Nov 2020 16:51:24



**US3152162**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Devan Myers (b) (4)	07 Dec 2020 21:45:27

**US3152162**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '7 Dec 2020'	Devan Myers (b) (4)	07 Dec 2020 21:45:27

**US3152162**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Contact Made (CONTACT MADE)'	Devan Myers (b) (4)	07 Dec 2020 21:45:27

**US3152162**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	Devan Myers (b) (4)	07 Dec 2020 21:45:27

**US3152162**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Devan Myers (b) (4)	07 Dec 2020 21:45:31

**US3152162**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User entered 'I'	System	07 Dec 2020 21:45:31

**US3152162**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	15 Jan 2021 17:33:38

**US3152162**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '11 Jan 2021'	Juliana DeVito (b) (4)	15 Jan 2021 17:33:38



**US3152162**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Contact Made (CONTACT MADE)'	Juliana DeVito (b) (4)	15 Jan 2021 17:33:38

**US3152162**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	Juliana DeVito (b) (4)	15 Jan 2021 17:33:38
	(b) (4)	

**US3152162**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	15 Jan 2021 17:33:44

**US3152162**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User entered 'I'	System	15 Jan 2021 17:33:44

**US3152162**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	08 Feb 2021 19:44:13

**US3152162**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '8 Feb 2021'	Juliana DeVito (b) (4)	08 Feb 2021 19:44:13

**US3152162**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Contact Made (CONTACT MADE)'	Juliana DeVito (b) (4)	08 Feb 2021 19:44:13

**US3152162**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	Juliana DeVito (b) (4)	08 Feb 2021 19:44:13
	(b) (4)	



**US3152162**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	08 Feb 2021 19:44:16

**US3152162**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:45:15
User entered 'I'	System	08 Feb 2021 19:44:16

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 19:40:58

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:40:58

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:40:58

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	29 Mar 2021 19:40:58

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:06



**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:41:06

US3152162

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:06



**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:43
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:55**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:41:06

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:27:55**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 19:41:12

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:27:55**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:12

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 19:41:16



**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:16

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:41:16

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:41:16

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 19:41:20

**US3152162**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:41:20

**US3152162**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	05 Apr 2021 15:47:47

**US3152162**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '05 Apr 2021'	Jemario Blackwell (b) (4)	05 Apr 2021 15:47:47

**US3152162**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	05 Apr 2021 15:47:47



**US3152162**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:55**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	Jemario Blackwell (b) (4)	05 Apr 2021 15:47:47

**US3152162**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	05 Apr 2021 15:47:53

**US3152162**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 15:47:53

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Azure Erskine (b) (4)	01 Feb 2021 21:46:57

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '01 Feb 2021'	Azure Erskine (b) (4)	01 Feb 2021 21:46:57

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[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 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Clinic (Clinic)'	Azure Erskine (b) (4)	01 Feb 2021 21:46:57

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:55**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 21:46:57

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '01 Feb 2021'	Azure Erskine (b) (4)	01 Feb 2021 21:47:24



**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	Azure Erskine (b) (4)	09 Apr 2021 19:19:37
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 12:29:29

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Azure Erskine (b) (4)	01 Feb 2021 21:47:24

US3152162

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:27:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:50:20
Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Field updated. ' (Site from DM).	Azure Erskine (b) (4) (b) (4)	09 Apr 2021 19:20:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	Azure Erskine (b) (4) (b) (4)	09 Apr 2021 19:19:37
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:31:47
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:29:29

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '01 Feb 2021'	Azure Erskine (b) (4)	01 Feb 2021 21:47:24

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'mRNA-1273 (mRNA-1273)'	Azure Erskine (b) (4)	01 Feb 2021 21:47:24

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'mRNA-1273 (mRNA-1273)'	Azure Erskine (b) (4)	01 Feb 2021 21:47:24

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'mRNA-1273 (mRNA-1273)'	Azure Erskine (b) (4)	01 Feb 2021 21:47:24

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	Azure Erskine (b) (4)	01 Feb 2021 21:47:24



**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User entered empty.	System	01 Feb 2021 21:47:24

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:55**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User entered empty.	System	01 Feb 2021 21:47:24

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Azure Erskine (b) (4)	01 Feb 2021 21:47:44

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '01 Feb 2021'	Azure Erskine (b) (4)	01 Feb 2021 21:47:44

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '10:33'	Azure Erskine (b) (4)	01 Feb 2021 21:47:44

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:55**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User entered '01 Feb 2021 10:33'	System	01 Feb 2021 21:47:44

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:27:55**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	Azure Erskine (b) (4)	01 Feb 2021 21:48:01

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:27:55**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '01 Feb 2021'	Azure Erskine (b) (4)	01 Feb 2021 21:48:01



**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:27:55**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '10:42'	Azure Erskine (b) (4)	01 Feb 2021 21:48:01

**US3152162**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:27:55**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:54:12
User entered '01 Feb 2021 10:42'	System	01 Feb 2021 21:48:01

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:27:55**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:50:34
DataPoint Verified.		08 Apr 2021 13:53:44
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:10:12

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23

US3152162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 21:12:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 21:12:56
Data point term sent to Coder	System	01 Oct 2020 21:12:12
User entered 'urinary tract infection'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 21:11:57



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered '28 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User entered empty.	System	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'No (N)' reason for change: New Information	Priscilla Buahin (b) (4)	09 Oct 2020 18:46:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered '03 Oct 2020' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	09 Oct 2020 18:46:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User entered empty.	System	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	01 Oct 2020 21:11:57



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:11:57



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

US3152162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 19:33:48
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you.' answered with 'updated per source' (Site from DM).	Juliana DeVito (b) (4)	25 Nov 2020 13:55:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	25 Nov 2020 13:55:03
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:17:33
User entered 'Not Applicable (NOT APPLICABLE)'		01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'Not Related (NOT RELATED)'	Juliana DeVito (b) (4)	25 Nov 2020 13:55:03
reason for change: Data Entry Error	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'None (NONE)'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

US3152162

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	01 Oct 2020 21:12:14
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 21:12:14
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	01 Oct 2020 21:11:57
User entered '1'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 21:11:57



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Priscilla Buahin (b) (4)	09 Oct 2020 18:46:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 02:02:28
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User entered '0'	System	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23
User entered '0'	System	01 Oct 2020 21:11:57

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:23

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:18
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:00:38
User entered	System	06 Apr 2021 15:58:08
'USA-US073-2021-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 15:58:08



US3152162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:16
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 21:40:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 21:40:58
Data point term sent to Coder	System	08 Apr 2021 17:58:59
DataPoint Un-verified.	Oyebisi Olanrewaju	08 Apr 2021 17:58:49
Coding entries removed.	(b) (4)	
	Oyebisi Olanrewaju	08 Apr 2021 17:58:49
User entered 'acute CEREBROVASCULAR ACCIDENT' reason for change: New Information	(b) (4)	08 Apr 2021 17:58:49
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:20
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 16:25:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 16:25:27
Data point term sent to Coder	System	05 Apr 2021 16:24:27
User entered 'cerebrovascular accident'	Oyebisi Olanrewaju	05 Apr 2021 16:23:50
	(b) (4)	

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:23
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:25
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:27
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:28
User entered '01 Apr 2021'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:30
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:23:50

US3152162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
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 'Cerebrovascular accident resolved after administration of TPA (tissue plasminogen activator) . Subject admitted for observation post TPA administration and monitoring post cerebrovascular accident. No other SAE occurred. ' (Site from Safety).	Priscilla Buahin (b) (4) (b) (4)	03 May 2021 17:14:05
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) (b) (4)	03 May 2021 13:51:25
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	08 Apr 2021 13:43:32
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:34
User entered '01 Apr 2021'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:41
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:43
User entered 'Grade 4 (Grade 4)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:46
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:48
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:50
User entered 'I'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:53
User entered 'I'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:01
User entered '01 Apr 2021'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

US3152162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'The requested pages have already been faxed to Safety_Moderna with number 866.599.1342 on 16Apr2021' (Site from Safety).	Priscilla Buahin (b) (4) (b) (4)	03 May 2021 16:03:48
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	03 May 2021 13:50:56
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	08 Apr 2021 13:46:03
User entered '03 Apr 2021'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:05
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:06
User entered '1'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:10
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:12
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:14
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:18
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:19
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:21
User entered 'Not Applicable (NOT APPLICABLE)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:24
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:26
User entered 'I'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:28
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:31
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

US3152162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm date subject stopped taking Bupropion as per medical records; also, please confirm subject's use of zolpidem and valacyclovir as concomitant medications. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 19:21:04
Query 'PV Query: Please confirm date subject stopped taking Bupropion as per medical records; also, please confirm subject's use of zolpidem and valacyclovir as concomitant medications. ' answered with 'Clarified with subject, Bupropion is ongoing on an as needed basis. Subject usually only takes it in winter for season related depression symptoms. Started taking Zolpidem as needed in 2001 for insomnia. Did not report at screening due to had not taken it for years. Recently resumed this medication due to loss of her son. Has been taking Valacyclovir as needed for cold sore since 1984. ConMed log updated. ' (Site from Safety).		23 Apr 2021 18:50:28
User opened query 'PV Query: Please confirm date subject stopped taking Bupropion as per medical records; also, please confirm subject's use of zolpidem and valacyclovir as concomitant medications. ' (Site from Safety).		23 Apr 2021 12:39:03
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).		19 Apr 2021 14:05:13
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		19 Apr 2021 14:05:11
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'sending redacted discharge summary via fax today, 16apr2021' (Site from Safety).	Juliana DeVito (b) (4) (b) (4)	16 Apr 2021 18:06:20
PRODUCTION RELEASE (v12.003 EAB) (1725)		1783 of 2129



US3152162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:55

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Subject had no underlying/pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 17:30:42
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.		15 Apr 2021 19:38:59
' (Site from Safety).		
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.		15 Apr 2021 19:26:06
' canceled (Site from Safety).		
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.		15 Apr 2021 19:18:17
' (Site from Safety).		
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.'		15 Apr 2021 19:18:08
canceled (Site from Safety).		
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.'		15 Apr 2021 19:09:52
(Site from Safety).		

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3152162

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [REDACTED]	15 Apr 2021 19:08:58
DataPoint Un-verified.	Shishir Khetan (b) (4) [REDACTED]	09 Apr 2021 02:12:17
User entered '01 APR 2021 SUBJECT AWOKE WITH DIPLOPIA and mild headache. ULTIMATELY REFERRED TO EMERGENCY ROOM BY PRIMARY CARE PROVIDER. MRI/MRA (01 APR) impression 5mm region of mildly diffuse bright signal/dark ADC signal within the right inferior PONS without underlying FLAIR hypersensitivity which could represent hyperacute infarct and mild irregularity of a left hypoplastic V4 segment left HA vertebral artery otherwise no significant stenosis or aneurysm greater than 3mm. Final diagnosis acute CEREBROVASCULAR ACCIDENT. TISSUE PLASMINOGEN ACTIVATOR ADMINISTERED. SUBJECT THEN ADMITTED TO ICU FOR OBSERVATION. DISCHARGED 03 APR 2021. Relevant studies: CBC with dif, CMP, Magnesium, Troponin, TSH, APPT/PT/INR within normal limits. SARS COV-2 Negative (01 APR 2021). Carotid doppler (01 APR 2021) impression- negative exam no plaque or velocity elevation seen. Transthoracic Echo with bubble study (01 APR 2021) impression- left ventricular ejection fraction normal estimated range of 60-65%, left ventricular cavity size appears normal, left ventricular wall thickness appears normal, unable to obtain RVSP due to insufficient tricuspid regurgitation jet, there is no significant valve disease, bubble study is inadequate to evaluate the atrial septum, no obvious source of embolism. EKG 12 lead (01 APR 2021) sinus tachycardia when compared to EKG 04 MAY 2018 incomplete right bundle branch block no longer present T wave inversion no longer evident in inferior leads . Narrative updated after medical records received and reviewed.' reason for change: New Information	Oyebisi Olanrewaju (b) (4) Oyebisi Olanrewaju (b) (4)	08 Apr 2021 19:06:10 08 Apr 2021 19:06:10

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:33
User entered '01 APR 2021 subject awoke with diplopia. Ultimately referred to emergency room by primary care provider. Work up in ER showed subject had a ischemic cerebrovascular accident. tissue plasminogen activator administered. Subject then admitted to ICU for observation. Discharged 03 APR 2021. Medical records to be requested.'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 16:23:50

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 16:23:50

US3152162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:53:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:53:09
Data point term sent to Coder	System	22 Apr 2021 17:51:16
User entered 'Post traumatic stress disorder'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '8 Apr 2021'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:50:16



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:50:16

US3152162

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:50:16



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16



**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '1'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 17:50:16

**US3152162**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 17:50:16



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 15:27:55**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:50:34
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:44
User entered 'Yes (Y)'		14 Aug 2020 00:44:03

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE, PRODUCTSYNONYM: LAMICTAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 00:46:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 00:46:14
Data point term sent to Coder	System	14 Aug 2020 00:45:10
User entered 'LAMICTAL'	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'BIPOLAR DISORDER'	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '150'	(b) (4), (b) (6)	14 Aug 2020 00:44:47

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 00:44:47

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'twice daily (BID)'	(b) (4), (b) (6)	14 Aug 2020 00:44:47



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:44:47

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 09:59:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		14 Aug 2020 00:46:46
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 00:44:47
User entered 'UN UNK 2001'	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:44:47



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 00:44:47

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 00:44:47

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: BUPROPION HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 07:09:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 07:09:24
Data point term sent to Coder	System	14 Aug 2020 00:46:11
User entered 'BU PROPION HCL'	(b) (4), (b) (6)	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'DEPRESSION'	(b) (4), (b) (6)	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '150'	(b) (4), (b) (6)	14 Aug 2020 00:45:42

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 00:45:42



US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:45:42

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 00:47:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 00:47:25
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Aug 2020 00:47:25
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 00:45:42
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:45:42

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:45:42

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 09:59:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		14 Aug 2020 00:47:22
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 00:45:42
User entered 'UN Feb 2020'	(b) (4), (b) (6)	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:45:42



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 00:47:25
User entered empty.	System	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Aug 2020 00:47:25
User entered empty.	System	14 Aug 2020 00:45:42

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Aug 2020 00:47:25
User entered empty.	System	14 Aug 2020 00:45:42

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 06:05:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 06:05:14
Data point term sent to Coder	System	14 Aug 2020 00:47:13
User entered 'ALBUTEROL HCL'	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'MILD ASTHMA'	(b) (4), (b) (6)	14 Aug 2020 00:46:29



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '2'	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'puff (PUFF)'	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'as needed (PRN)'	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:46:29

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 10:00:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		14 Aug 2020 00:47:38
answered with 'ONGOING' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	14 Aug 2020 00:46:29
User entered 'UN UNK 1984'	(b) (4), (b) (6)	14 Aug 2020 00:46:29



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 00:46:29

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 00:46:29

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 21:13:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 21:13:58
Data point term sent to Coder	System	01 Oct 2020 21:13:15
User entered 'nitrofurantoin mono'	(b) (4), (b) (6)	01 Oct 2020 21:13:13



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'urinary tract infection'	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '100'	(b) (4), (b) (6)	01 Oct 2020 21:13:13

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'twice daily (BID)'	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 21:13:13



US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '29 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)' reason for change: New Information	Priscilla Buahin (b) (4)	09 Oct 2020 18:48:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '3 Oct 2020' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	09 Oct 2020 18:48:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User entered '2'	System	01 Oct 2020 21:13:13

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User entered '1'	System	01 Oct 2020 21:13:13



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:12
User entered '804 (804)'	System	01 Oct 2020 21:13:13

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 21:50:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 21:50:59
Data point term sent to Coder	System	07 Dec 2020 21:50:30
User entered 'Influenza Vaccination'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Yes (Y)'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Prophylaxis for influenza virus'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '0.5'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'mL (mL)'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'once (ONCE)'	Devan Myers (b) (4)	07 Dec 2020 21:50:11



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'Intramuscular (INTRAMUSCULAR)'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered empty.	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '11 Nov 2020'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '0'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered '11 Nov 2020'	Devan Myers (b) (4)	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
User entered 'No (N)'	Devan Myers (b) (4)	07 Dec 2020 21:50:11



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User entered empty.	System	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User entered empty.	System	07 Dec 2020 21:50:11

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:15:17
User entered empty.	System	07 Dec 2020 21:50:11

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:55

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: ALTEPLASE, PRODUCTSYNONYM: TISSUE PLASMINOGEN ACTIVATOR, RECOMBINATIVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:57:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:57:39
User signature succeeded.	Shishir Khetan (b) (4) (b) (4)	09 Apr 2021 02:12:21
Data point term sent to Coder	System	08 Apr 2021 17:57:58
Coding entries removed.	Oyebisi Olanrewaju	08 Apr 2021 17:57:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4)	08 Apr 2021 13:46:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: ENZYMES, PRODUCT: ALTEPLASE, PRODUCTSYNONYM: TISSUE PLASMINOGEN ACTIVATOR, RECOMBINATIVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:33:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:33:54
Data point term sent to Coder	System	05 Apr 2021 16:26:32
User entered 'tissue plasminogen activator'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:47:01
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:25:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 16:25:51
User entered 'No (N)' reason for change: Data Entry Error	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:51
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 16:25:46
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Un-verified.	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 17:57:38
User entered 'Acute CEREBROVASCULAR ACCIDENT' reason for change: New Information	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 17:57:38
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:47:03
User entered 'ischemic cerebrovascular accident'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Un-verified.	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 17:57:24
User entered '85.1' reason for change: New Information	Oyebisi Olanrewaju (b) (4)	08 Apr 2021 17:57:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:47:04
User entered 'unk'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:47:07
User entered 'mg (mg)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:47:09
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:47:12
User entered 'once (ONCE)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:47:14
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:25
User entered 'Intravenous (INTRAVENOUS)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:51
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
User entered '01 Apr 2021'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:55
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:57
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:58
User entered '01 Apr 2021'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:01
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:25:46

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 16:25:46

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:17:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:17:54
Data point term sent to Coder Coding entries removed.	System Oyebisi Olanrewaju (b) (4)	06 Apr 2021 13:17:01 06 Apr 2021 13:16:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 16:28:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 16:28:30
Data point term sent to Coder User entered 'plavix'	System Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:33 05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:23
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:27
User entered 'CEREBROVASCULAR Accident PROPHYLAXIS' reason for change: Data Entry Error	Oyebisi Olanrewaju (b) (4)	06 Apr 2021 13:16:23
User entered 'cerebrovascular prophylaxis'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:29
User entered '75'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:31
User entered 'mg (mg)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:36
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:40
User entered 'once daily (QD)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:42
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:46
User entered 'Oral (ORAL)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:47
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:49
User entered '03 Apr 2021'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:53
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 17:56:38
Signature has been broken.		22 Apr 2021 17:56:38
User entered 'No (N)' reason for change: New Information		22 Apr 2021 17:56:38
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:49:56
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 17:56:38
Signature has been broken.		22 Apr 2021 17:56:38
User entered '21 Apr 2021' reason for change: New Information		22 Apr 2021 17:56:38
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:00
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:05
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 16:26:38

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 16:26:38

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:17:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:17:54
Data point term sent to Coder Coding entries removed.	System Oyebisi Olanrewaju (b) (4)	06 Apr 2021 13:17:01 06 Apr 2021 13:16:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:33:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:33:44
Data point term sent to Coder User entered 'aspirin'	System Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:32 05 Apr 2021 16:27:10



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:15
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:18
User entered 'CEREBROVASCULAR Accident PROPHYLAXIS' reason for change: Data Entry Error	Oyebisi Olanrewaju (b) (4)	06 Apr 2021 13:16:39
User entered 'cerebrovascular prophylaxis'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:20
User entered '81'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:23
User entered 'mg (mg)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:25
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:28
User entered 'once daily (QD)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:30
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:32
User entered 'Oral (ORAL)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:39
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:40
User entered '03 Apr 2021'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:42
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:44
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:46
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:50
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 16:27:10

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 16:27:10



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 16:27:10

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 14:10:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 14:10:50
Data point term sent to Coder Coding entries removed.	System Oyebisi Olanrewaju (b) (4)	06 Apr 2021 13:17:04 06 Apr 2021 13:16:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:29:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:29:55
Data point term sent to Coder User entered 'lipitor'	System Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:28:34 05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:02
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:04
User entered 'CEREBROVASCULAR Accident PROPHYLAXIS' reason for change: Data Entry Error	Oyebisi Olanrewaju (b) (4)	06 Apr 2021 13:16:55
User entered 'cerebrovascular prophylaxis'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:14
User entered '80'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:20
User entered 'mg (mg)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:26
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:29
User entered 'once daily (QD)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:32
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:33
User entered 'Oral (ORAL)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:35
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:36
User entered '03 Apr 2021'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:38
User entered '0'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:41
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:42
User entered empty.	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:12:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:51:44
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	05 Apr 2021 16:27:35



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 16:27:35

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 16:27:35

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TOPAMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:54:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 02:54:39
Data point term sent to Coder	System	22 Apr 2021 17:56:22
User entered 'Topamax'	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Post traumatic stress disorder, depression, bipolar disorder'	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '25'	(b) (4), (b) (6)	22 Apr 2021 17:55:52

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Apr 2021 17:55:52



US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Apr 2021 17:55:52

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '8 Apr 2021'	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 17:55:52



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:55:52

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 17:55:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Apr 2021 17:55:58
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Apr 2021 17:55:58
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Apr 2021 17:55:52
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 17:55:52

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 17:55:52

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: PRAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:52:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:52:56
Data point term sent to Coder	System	22 Apr 2021 18:52:06
User entered 'Prazosin'	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'post traumatic stress disorder'	(b) (4), (b) (6)	22 Apr 2021 18:51:25



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '1'	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Apr 2021 18:51:25

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '21 Apr 2021'	(b) (4), (b) (6)	22 Apr 2021 18:51:25



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 18:51:25

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 18:51:25

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:52:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:52:59
Data point term sent to Coder	System	23 Apr 2021 18:51:45
User entered 'Zolpidem'	(b) (4), (b) (6)	23 Apr 2021 18:51:45



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Insomnia'	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '12.5'	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	23 Apr 2021 18:51:45



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'UN UNK 2001'	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:51:45

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:51:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 18:51:54
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 18:51:54
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:51:45
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:51:45

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:51:45



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:51:45

US3152162

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:55:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 18:55:00
Data point term sent to Coder	System	23 Apr 2021 18:53:46
User entered 'Valacyclovir'	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'herpes labialis'	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '2000'	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Apr 2021 18:53:14



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'UN UNK 1984'	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '0'	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 18:53:14



**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:53:14

**US3152162**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:55**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 18:53:14

US3152162

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:27:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	17 Apr 2021 21:09:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:01:18
User closed query 'Subject had MRI, vascular ultrasound, TTE, per Med records. Please review and update' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:01:16
Query 'Subject had MRI, vascular ultrasound, TTE, per Med records. Please review and update' answered with 'please provider further clarification if diagnostic procedures are to be entered or only treatment procedures. Thanks ' (Site from CRA).	Oyebisi Olanrewaju (b) (4)	09 Apr 2021 18:57:25
User opened query 'Subject had MRI, vascular ultrasound, TTE, per Med records. Please review and update' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 19:53:04
Query 'Subject had MRI per Med records. Please update' canceled (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 19:48:38
User opened query 'Subject had MRI per Med records. Please update' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 19:44:35
User entered 'No (N)'	Juliana DeVito (b) (4) (b) (4)	08 Feb 2021 19:48:56

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'USA-US073-2021-MRNA-1273-P301000011'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08



**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Brandon'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'SHISHIR' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Brandon'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Essink'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'KHETAN' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Essink'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered '3319 N 107th'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered '1201 Seven Locks Rd, Suite 111,'	(b) (4)	
reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered '3319 N 107th'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Omaha'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'ROCKVILLE' reason for change:	(b) (4)	
Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Omaha'	System	06 Apr 2021 15:58:08



US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered empty.	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
User entered 'MARYLAND'	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
	(b) (4)	

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered '68134'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered '20854' reason for change: Data Entry Error	(b) (4) Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered '68134'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
User entered 'US'	System	06 Apr 2021 16:01:30

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 19:22:21
User entered '2'	System	09 Apr 2021 14:09:20
User entered '1'	System	06 Apr 2021 16:01:30

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'USA-US073-2021-MRNA-1273-P301000011'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08



**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Brandon'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'SHISHIR' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Brandon'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Essink'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'KHETAN' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Essink'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered '3319 N 107th'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered '1201 Seven Locks Rd, Suite 111,'	(b) (4)	
reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered '3319 N 107th'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Omaha'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'ROCKVILLE' reason for change:	(b) (4)	
Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Omaha'	System	06 Apr 2021 15:58:08



US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered empty.	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
User entered 'MARYLAND'	Priscilla Buahin (b) (4) (b) (4)	06 Apr 2021 20:39:39

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered '68134'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered '20854' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered '68134'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
User entered 'US'	System	06 Apr 2021 16:01:30

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 19:22:21
User entered '2'	System	09 Apr 2021 14:09:20
User entered '1'	System	06 Apr 2021 16:01:30

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:27:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
User entered '06/Apr/2021 12:01'	System	06 Apr 2021 16:01:30

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:27:55

**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.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
User entered '1'		06 Apr 2021 16:01:30

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'USA-US073-2021-MRNA-1273-P301000011'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08



**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Brandon'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'SHISHIR' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Brandon'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Essink'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'KHETAN' reason for change: Data Entry Error	(b) (4)	
	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Essink'	System	06 Apr 2021 15:58:08



US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered '3319 N 107th'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered '1201 Seven Locks Rd, Suite 111,'	(b) (4)	
reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered '3319 N 107th'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Omaha'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'ROCKVILLE' reason for change:	(b) (4)	
Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Omaha'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered empty.	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
User entered 'MARYLAND'	Priscilla Buahin (b) (4) (b) (4)	06 Apr 2021 20:39:39

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered '68134'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered '20854' reason for change: Data Entry Error	(b) (4) Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered '68134'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
User entered 'US'	System	06 Apr 2021 16:01:30

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 19:22:21
User entered '2'	System	09 Apr 2021 14:09:20
User entered '1'	System	06 Apr 2021 16:01:30

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:27:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
User entered '09/Apr/2021 10:09'	System	09 Apr 2021 14:09:20

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:27:55

**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.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
User entered 'I'		09 Apr 2021 14:09:20



**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'USA-US073-2021-MRNA-1273-P301000011'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'Yes (Y)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:01
Reviewed for Safety.		06 Apr 2021 16:01:16
User entered 'No (N)'	System	06 Apr 2021 15:58:08



US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Brandon'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'SHISHIR' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Brandon'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Essink'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'KHETAN' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Essink'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered '3319 N 107th'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered '1201 Seven Locks Rd, Suite 111,'	(b) (4)	
reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered '3319 N 107th'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered 'Omaha'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered 'ROCKVILLE' reason for change:	(b) (4)	
Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered 'Omaha'	System	06 Apr 2021 15:58:08

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered empty.	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
User entered 'MARYLAND'	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
	(b) (4)	

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:55

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:58:33
Un-reviewed for Safety.	System	09 Apr 2021 14:09:20
DataPoint Un-verified.	System	09 Apr 2021 14:09:20
User entered '68134'	System	09 Apr 2021 14:09:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
Un-reviewed for Safety.	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
User entered '20854' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	06 Apr 2021 20:39:39
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 16:01:16
User entered '68134'	System	06 Apr 2021 15:58:08

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:09:08
DataPoint Verified.		08 Apr 2021 13:54:01
User entered 'US'	System	06 Apr 2021 16:01:30

**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:55**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 19:22:21
User entered '2'	System	09 Apr 2021 14:09:20
User entered '1'	System	06 Apr 2021 16:01:30



**US3152162**

**Folder: SAE USA-US073-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:27:55**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered '26/Apr/2021 15:22'	System	26 Apr 2021 19:22:21

US3152162

Folder: SAE USA-US073-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:27:55

**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.	Shishir Khetan (b) (4)	28 Apr 2021 17:11:19
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 19:22:21