

US3152194 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:29:43

All time stamps listed in this document are displayed in GMT

US3152194

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:05:24

Generated On: 09 Jun 2021 15:29:43

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[Participant ID](#)

US3152194

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

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US3152194

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:36:10

Generated On: 09 Jun 2021 15:29:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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 04:35:56

Generated On: 09 Jun 2021 15:29:43

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	54
Age Units	YEARS
Age (Derived)	54
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 04:36:10

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	14 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 04:36:10

Generated On: 09 Jun 2021 15:29:43

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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 04:36:10

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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 17:21:04

Generated On: 09 Jun 2021 15:29:43

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
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 17:21:04

Generated On: 09 Jun 2021 15:29:43

Condition	L4-L5 DISCECTOMY
Start date (dd MMM yyyy)	UN AUG 2017
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 AUG 2017
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2017
Start Year (derived)	2017
Stop Month and Year (derived)	AUG 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

Condition	L4-L5 DISC BULGE IMPINGEMENT
Start date (dd MMM yyyy)	UN UNK 2016
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 AUG 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	AUG 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

Condition	HASHIMOTO'S THYROIDITIS
Start date (dd MMM yyyy)	UN JAN 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 04:36:11

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	8:49 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 8:49
Height (xxx.x)	170.1 cm
Weight (xxx.x)	65.9 kg
BMI (xxx.x)	22.77597 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 04:36:10

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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 04:35:56

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Date of assessment (dd MMM yyyy) 14 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) \_\_\_\_\_  
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 04:36:10

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	14 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 04:36:10

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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 04:36:10

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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 04:36:11

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

Visit date (dd MMM yyyy)	14 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 04:36:11

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What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 104261

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 04:36:11

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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 04:36:11

Generated On: 09 Jun 2021 15:29:43

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)	14 AUG 2020
Time of assessment (00:00-23:59)	8:49 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 8:49
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 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)	85 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 04:36:11

Generated On: 09 Jun 2021 15:29:43

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)	14 AUG 2020
Time of assessment (00:00-23:59)	10:59 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 10:59
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 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)	79 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 04:36:11

Generated On: 09 Jun 2021 15:29:43

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 04:36:11

Generated On: 09 Jun 2021 15:29:43

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 04:36:11

Generated On: 09 Jun 2021 15:29:43

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 10:25 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 10:25

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	8:59 (24 HR)
Collection date and time (derived)	14 AUG 2020 8:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:35	14 AUG 2020 9:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

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 15:29:43

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 11:00

PC Open Date & Time

14 AUG 2020 10:45

PC Close Date & Time

14 AUG 2020 13:15

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.7 °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	14 AUG 2020 17:21
PC Open Date & Time	14 AUG 2020 14:10
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

15 AUG 2020 15:45

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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 AUG 2020 18:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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 18:58

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 17:14

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 12:00

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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 12:06

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**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

14 AUG 2020 11:02

PC Open Date & Time

14 AUG 2020 10:45

PC Close Date & Time

14 AUG 2020 13:15

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 17:21

PC Open Date & Time

14 AUG 2020 14:10

PC Close Date & Time

15 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 15:46

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

**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

16 AUG 2020 18:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

**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

17 AUG 2020 18:58

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

**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

18 AUG 2020 17:15

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

**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 12:00

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

**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 12:06

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**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 ☐

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 11:02
PC Open Date & Time	14 AUG 2020 10:45
PC Close Date & Time	14 AUG 2020 13:15

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**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 ☐

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 17:22
PC Open Date & Time	14 AUG 2020 14:10
PC Close Date & Time	15 AUG 2020 11:59



US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**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 ☒

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 15:46
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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

50 of 1609

EAB) (1725)

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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

52 of 1609

EAB) (1725)

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 18:58
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:43

**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

EAB) (1725)

54 of 1609

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 17:15
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59



US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 1609

EAB) (1725)

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 1609

EAB) (1725)

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 12:06
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3152194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3152194

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

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*

US3152194

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3152194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3152194

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152194

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3152194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

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)	11 SEP 2020
Time of assessment (00:00-23:59)	13:23 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:23
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)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3152194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

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)	11 SEP 2020
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:01
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3152194

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3152194

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	11 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3152194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 14:31 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 14:31

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



US3152194

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	13:41 (24 HR)
Collection date and time (derived)	11 SEP 2020 13:41

US3152194

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:36	11 SEP 2020 13:36
Nasopharyngeal Swab 2	No		

US3152194

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 15:02

PC Open Date & Time

11 SEP 2020 14:51

PC Close Date & Time

11 SEP 2020 17:21

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**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 ☒

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 22:47
PC Open Date & Time	11 SEP 2020 18:16
PC Close Date & Time	12 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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 21:44

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 06:15

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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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

97.5 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

15 SEP 2020 12:00

---

PC Open Date & Time

15 SEP 2020 12:00

---

PC Close Date & Time

16 SEP 2020 11:59

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US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:43

**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

98.0 °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

17 SEP 2020 07:10

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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 SEP 2020 19:19

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 15:03

PC Open Date & Time

11 SEP 2020 14:51

PC Close Date & Time

11 SEP 2020 17:21

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 22:47

PC Open Date & Time

11 SEP 2020 18:16

PC Close Date & Time

12 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 21:44

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

**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

13 SEP 2020 19:59

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 06:15

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

**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

15 SEP 2020 12:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 07:10

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

**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

17 SEP 2020 19:20

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**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 ☐

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 15:03
PC Open Date & Time	11 SEP 2020 14:51
PC Close Date & Time	11 SEP 2020 17:21

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**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 ☐

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 22:48
PC Open Date & Time	11 SEP 2020 18:16
PC Close Date & Time	12 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 21:44
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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

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EAB) (1725)

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:00
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 06:15
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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 ☒

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 12:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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 ☒



US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 07:11
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:43

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:43

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:20
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3152194

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3152194

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152194

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3152194

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:35:56

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152194

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:44:21

Generated On: 09 Jun 2021 15:29:43

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3152194

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:44:21

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152194

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

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

US3152194

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

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)	08:21 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 08:21
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3152194

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3152194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

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)	08:50 (24 HR)
Collection date and time (derived)	9 OCT 2020 08:50

US3152194

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 04:36:11

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 06:31:33

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3152194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

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 <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 OCT 2020 06:34:57
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59



US3152194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

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 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	28 OCT 2020 07:20:17
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3152194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

**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 07:23:16

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3152194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 07:14:19
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3152194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

**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

25 NOV 2020 06:44:46

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3152194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 06:38:43

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3152194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

**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

07 DEC 2020 09:39:30

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3152194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 09:54:05

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3152194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 DEC 2020 12:06:03
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59



US3152194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

**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

28 DEC 2020 17:18:06

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3152194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 12:14:02
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3152194

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 00:01:38

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

**US3152194**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 15:29:43**

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

US3152194

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:29:43

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3152194

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3152194

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:29:43

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3152194

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3152194

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3152194

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

**US3152194**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:29:43**

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"/>

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3152194

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

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 UNBLND\_DECIDE

US3152194

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

Date of updated informed consent (dd MMM yyyy)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (dd MMM yyyy)	05 NOV 2020
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3152194

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3152194

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)



US3152194

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:05:24

Generated On: 09 Jun 2021 15:29:43

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3152194

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 02:32:18

Generated On: 09 Jun 2021 15:29:43

AEID	USA-US073-2020-MRNA-1273-P30 1000002
Adverse event	BILATERAL PULMONARY EMBOLISM
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)	21 SEP 2020
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)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	145 of 1609

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 02:32:18

Generated On: 09 Jun 2021 15:29:43

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	CONDITION IS STABLE AND ONGOING BUT PATIENT MUST TAKE XARELTO FOR PE PROPHYLAXIS.

Narrative

US3152194

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 02:32:18

Generated On: 09 Jun 2021 15:29:43

PT REPORTED THAT SHE HAD ONE EPISODE OF RIGHT SIDED CHEST PAIN ON 21 SEP, 2020, WHICH LASTED FOR A FEW HOURS THEN RESOLVED SPONTANEOUSLY. SHE DID NOT SEEK MEDICAL ATTENTION BACK THEN BUT WAS TREATED WITH MEDROL DOSE PACK (PT IS AN MD). REPORTS HER ORTHOPEDIC COLLEAGUE ORDERED A CT SCAN FOR HER BACK PAIN (HXO L4-L5 DISCECTOMY) WHICH INCIDENTALLY REVEALED ACUTE AND SUBACUTE PULMONARY EMBOLISM ON 02 OCT, 2020. PT WAS EVALUATED BY HEMATOLOGY ON 02 OCT, 2020 AND STARTED ON LOVENOX INJECTIONS TWICE DAILY FOR 14 DAYS. PLANS TO START XARELTO TREATMENT UPON COMPLETION OF LOVENOX. STATES SHE IS ASYMPTOMATIC AT THIS TIME. MEDICAL RECORDS PENDING.

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)	

US3152194

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 02:32:18

Generated On: 09 Jun 2021 15:29:43

AEID

Adverse event

UNSPECIFIED RIGHT CHEST  
PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 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)

21 SEP 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 ☐

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EAB) (1725)

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US3152194

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 02:32:18

Generated On: 09 Jun 2021 15:29:43

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

US3152194

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 02:32:18

Generated On: 09 Jun 2021 15:29:43

AEID

Adverse event

PLEURAL EFFUSION

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)

22 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)

02 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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 09 Apr 2021 02:32:18

Generated On: 09 Jun 2021 15:29:43

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____



US3152194

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Apr 2021 02:32:18

Generated On: 09 Jun 2021 15:29:43

AEID	USA-US073-2020-MRNA-1273-P30 1000002
Adverse event	BILATERAL PULMONARY INFARCTS
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)	02 OCT 2020
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)	16 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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 (4)

Data signed: (b) (4) 09 Apr 2021 02:32:18

Generated On: 09 Jun 2021 15:29:43

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	XARELTO FOR PROPHYLAXIS
Narrative	AE TERM DIVIDED PER SPONSORS REQUEST INITIAL AE TERMED BILATERAL PULMONARY EMBOLISM WITH BILATERAL INFARCTS
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Data signed:** (b) (4) 09 Apr 2021 02:32:18

**Generated On: 09 Jun 2021 15:29:43**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:29:43

---

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

Yes ☒

No ☐

---

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

---

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Name of Medication CARVEDILOL ER

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

	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)	UN UNK 2019	
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"/>

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Name of Medication VITAMIN B-12

Prophylaxis Yes ☐  
No ☒

Indication NUTRITIONAL SUPPLEMENT

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 ☐  
Intraocular ☐

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US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

	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 2019	
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"/>



US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Name of Medication ALIGN PROBIOTIC

Prophylaxis Yes ☐  
No ☒

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

	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)	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"/>

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Name of Medication MEDROL DOSE PACK

Prophylaxis Yes ☐  
No ☒

Indication UNSPECIFIED RIGHT CHEST  
PAIN

Dose per administration 4

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

DOSE PACK  
6 TABS  
5 TABS  
4 TABS  
3 TABS  
2 TABS  
1 TAB

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Route of administration	Oral <input checked="" type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>
	Intramuscular <input type="radio"/>
	Respiratory (Inhalation) <input type="radio"/>
	Intralesional <input type="radio"/>
	Intraperitoneal <input type="radio"/>
	Nasal <input type="radio"/>
	Vaginal <input type="radio"/>
	Rectal <input type="radio"/>
	Intravenous <input type="radio"/>
	Intravenous Bolus <input type="radio"/>
	Intravenous Drip <input type="radio"/>
	Other <input type="radio"/>
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	21 SEP 2020
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 27 SEP 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 (5)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Name of Medication LOVENOX

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL PULMONARY  
EMBOLI WITH PULMONARY  
INFARCTS

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

	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)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Name of Medication CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 600

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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EAB) (1725)

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US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

	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 APR 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"/>



US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

Name of Medication XARELTO

Prophylaxis Yes ☒  
No ☐

Indication PULMONARY EMBOLISM  
PROPHYLAXIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Mar 2021 13:16:03

Generated On: 09 Jun 2021 15:29:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 OCT 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"/>

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:29:43

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 OCT 2020	ECHOCARDIOGRAM	Adverse Event	
2 OCT 2020	FACTOR V LEIDEN	Adverse Event	
2 OCT 2020	PROTEIN C	Adverse Event	
2 OCT 2020	LUPUS ANTICOAGULANT PANEL	Adverse Event	
2 OCT 2020	PROTEIN S	Adverse Event	
2 OCT 2020	ANTITHROMBIN III ANTIGEN PANEL	Adverse Event	
2 OCT 2020	CARDIOLIPIN ANTIBODY PANEL	Adverse Event	
2 OCT 2020	BETA 2 GLYCOPROTEIN 1	Adverse Event	
2 OCT 2020	HOMOCYSTEINE PANEL	Adverse Event	
2 OCT 2020	COMPREHENSIVE METABOLIC PANEL	Adverse Event	
2 OCT 2020	CBC WITH AUTO DIFFERENTIALS	Adverse Event	
7 OCT 2020	VENOUS DOPPLER ULTRASOUND DVT PROTOCOL BILATERAL LEGS	Adverse Event	
6 OCT 2020	COMPUTED TOMOGRAPHY ABDOMEN AND PELVIS WITH CONTRAST	Adverse Event	
2 OCT 2020	COMPUTED TOMOGRAPHY CHEST WITH CONTRAST	Adverse Event	

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Data signed: (b) (4) 19 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:29:43

---

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 SEP 2020	MAGNETIC RESONANCE IMAGING THORACIC SPINE WITHOUT CONTRAST	Adverse Event	

---

US3152194

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 17 Mar 2021 01:50:22

Generated On: 09 Jun 2021 15:29:43

Date of study discontinuation/completion (dd MMM yyyy) 15 JAN 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input checked="" type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

SUBJECT RECEIVED AN EUA OUTSIDE OF STUDY ON 16DEC2020.

If reason for discontinuation is Death, main cause of death

Adverse event	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>
Unknown	<input type="checkbox"/>

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9
Date of submission (Pre-filled from custom function)	05/OCT/2020 08:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9
Date of submission (Pre-filled from custom function)	28/OCT/2020 13:05
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

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9
Date of submission (Pre-filled from custom function)	19/NOV/2020 14:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9
Date of submission (Pre-filled from custom function)	30/NOV/2020 11:10
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

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9
Date of submission (Pre-filled from custom function)	21/DEC/2020 11:45
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

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9
Date of submission (Pre-filled from custom function)	28/DEC/2020 20:26
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

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9
Date of submission (Pre-filled from custom function)	05/MAR/2021 09:52
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

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9
Date of submission (Pre-filled from custom function)	23/MAR/2021 11:22
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

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 17:21:04

Generated On: 09 Jun 2021 15:29:43

SAEID	USA-US073-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input 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)	9
Date of submission (Pre-filled from custom function)	09/APR/2021 08:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



Audit

US3152194 (Prod: Meridian Clinical Research-(Rockville Maryland) - Platinum - PPDS)

**US3152194**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:29:43**

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'US3152194'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 12:44:24

**US3152194**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31

US3152194

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User closed query ' Per GCL Lab Reconciliation: Swab: Sample dated 11 SEP 2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 10:20:18
Query ' Per GCL Lab Reconciliation: Swab: Sample dated 11 SEP 2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'Sample collected on 11SEP2020 via requisition form 1F620975230' (Site from DM).	Azure Erskine (b) (4)	04 Nov 2020 18:27:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:25
User opened query ' Per GCL Lab Reconciliation: Swab: Sample dated 11 SEP 2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).		22 Oct 2020 07:48:29
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:10

US3152194

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:19
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 12:44:25

US3152194

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:43

[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 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:22
User entered 'Clinic (Clinic)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:10
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'SCRN'	System	14 Aug 2020 14:33:10

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 12:44:25



US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered '54'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:43**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'YEARS'	System	14 Aug 2020 14:33:38

**US3152194**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:43**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '54'	System	14 Aug 2020 14:35:06

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered 'Female (F)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:29:43**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered 'I'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered '0'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered '0'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	



US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered '0'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered '0'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered '0'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered empty.	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered '0'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

US3152194

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:43

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:35
User entered '0'	Jemario Blackwell (b) (4)	14 Aug 2020 14:33:38
	(b) (4)	

US3152194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:50
User entered '14 Aug 2020'	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:06
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'Aug 2020'	System	14 Aug 2020 14:35:06



**US3152194**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '2020'	System	14 Aug 2020 14:35:06

US3152194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:50
User entered 'Amendment 2 (2)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:06
	(b) (4)	

US3152194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:50
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:06
	(b) (4)	

US3152194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:50
User entered empty.	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:06
	(b) (4)	

US3152194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:50
User entered empty.	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:06
	(b) (4)	

US3152194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:50
User entered 'No (N)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:06
	(b) (4)	

US3152194

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:50
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 12:44:25

**US3152194**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:29:43**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '1'	System	14 Aug 2020 14:35:16



US3152194

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:05:57
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:16
	(b) (4)	

US3152194

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:29:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:04
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:40:41
	(b) (4)	

US3152194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:43:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:43:23
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 14:42:06
User entered 'Hypertension'	Azure Erskine (b) (4)	21 Aug 2020 14:41:29
	(b) (4)	

US3152194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered 'un UNK 2008'	Azure Erskine (b) (4)	21 Aug 2020 14:41:29
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:41:29
	(b) (4)	

US3152194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:41:29
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
Signature has been broken.	Juliana DeVito (b) (4)	08 Apr 2021 13:17:01
	(b) (4)	
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:41:29
	(b) (4)	

US3152194

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:41:29
	(b) (4)	



**US3152194**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'Jan 2008'	System	21 Aug 2020 14:41:29

**US3152194**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '2008'	System	21 Aug 2020 14:41:29

**US3152194**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered empty.	System	21 Aug 2020 14:41:29

**US3152194**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered empty.	System	21 Aug 2020 14:41:29

US3152194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Lumbar discectomy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:44:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 14:44:08
Data point term sent to Coder	System	21 Aug 2020 14:42:07
User entered 'L4-L5 discectomy'	Azure Erskine (b) (4)	21 Aug 2020 14:42:06

US3152194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered 'un Aug 2017'	Azure Erskine (b) (4)	21 Aug 2020 14:42:06
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:42:06
	(b) (4)	

US3152194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:42:06
	(b) (4)	



US3152194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered 'un Aug 2017'	Azure Erskine (b) (4)	21 Aug 2020 14:42:06
	(b) (4)	

US3152194

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:42:06
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'Aug 2017'	System	21 Aug 2020 14:42:06

**US3152194**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '2017'	System	21 Aug 2020 14:42:06

**US3152194**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'Aug 2017'	System	21 Aug 2020 14:42:06

**US3152194**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '2017'	System	21 Aug 2020 14:42:06

US3152194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Lumbar disc herniation - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:32:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 12:32:48
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 14:43:08
User entered 'L4-L5 Disc Bulge Impingement'	Azure Erskine (b) (4)	21 Aug 2020 14:43:08
	(b) (4)	

US3152194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered 'un UNK 2016'	Azure Erskine (b) (4)	21 Aug 2020 14:43:08
	(b) (4)	



**US3152194**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:43:08
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:43:08
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:43**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered 'un Aug 2017'	Azure Erskine (b) (4)	21 Aug 2020 14:43:08
	(b) (4)	

US3152194

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:06:27
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:43:08
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'Jan 2016'	System	21 Aug 2020 14:43:08

**US3152194**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '2016'	System	21 Aug 2020 14:43:08

**US3152194**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'Aug 2017'	System	21 Aug 2020 14:43:08

**US3152194**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '2017'	System	21 Aug 2020 14:43:08



US3152194

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:56:41
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Acute and chronic thyroiditis, PT: Autoimmune thyroiditis, LLT: Hashimoto's thyroiditis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 21:19:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 21:19:41
	(b) (4)	
Data point term sent to Coder	System	04 Mar 2021 21:04:39
User entered 'HASHIMOTO's THYROIDITIS'	Juliana DeVito (b) (4)	04 Mar 2021 21:03:54
reason for change: Data Entry Error	(b) (4)	
Data point term sent to Coder	System	04 Mar 2021 21:03:38
User entered 'hashimoto thyroiditis'	Juliana DeVito (b) (4)	04 Mar 2021 21:03:34
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:56:41
User entered 'un Jan 2020'	Juliana DeVito (b) (4)	04 Mar 2021 21:03:34
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:56:41
User entered '0'	Juliana DeVito (b) (4)	04 Mar 2021 21:03:34
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:56:41
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	04 Mar 2021 21:03:34
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:43**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:56:41
User entered empty.	Juliana DeVito (b) (4)	04 Mar 2021 21:03:34
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 12:56:41
User entered '0'	Juliana DeVito (b) (4)	04 Mar 2021 21:03:34
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'Jan 2020'	System	04 Mar 2021 21:03:34

**US3152194**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '2020'	System	04 Mar 2021 21:03:34



**US3152194**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered empty.	System	04 Mar 2021 21:03:34

**US3152194**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered empty.	System	04 Mar 2021 21:03:34

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered '8:49'	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '14 Aug 2020 8:49'	System	21 Aug 2020 14:40:24

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered '170.1' cm	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	
DataPoint set to visible.	System	14 Aug 2020 14:35:16

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered '65.9' kg	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	
DataPoint set to visible.	System	14 Aug 2020 14:35:16



**US3152194**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
Amendment Manager: User entered '22.77597'	System	16 Sep 2020 23:56:42
User entered '22.8'	System	21 Aug 2020 14:40:24
DataPoint set to visible.	System	14 Aug 2020 14:35:16

**US3152194**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'kg/m2'	System	21 Aug 2020 14:40:24
DataPoint set to visible.	System	14 Aug 2020 14:35:16

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
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).		15 Sep 2020 14:48:35
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)	12 Sep 2020 14:05:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Sep 2020 14:05:14
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)	06 Sep 2020 17:35:01
User entered '36.6' C	Azure Erskine (b) (4)	21 Aug 2020 14:40:24

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:14
	(b) (4)	
User entered 'Oral (Oral)'	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:14
	(b) (4)	
User entered '53'	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'bpm'	System	21 Aug 2020 14:40:24

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:14
	(b) (4)	
User entered '14'	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	



**US3152194**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'breaths/min'	System	21 Aug 2020 14:40:24

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:14
	(b) (4)	
User entered '129'	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'mmHg'	System	21 Aug 2020 14:40:24

US3152194

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:14
	(b) (4)	
User entered '85'	Azure Erskine (b) (4)	21 Aug 2020 14:40:24
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'mmHg'	System	21 Aug 2020 14:40:24

**US3152194**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13

**US3152194**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13

US3152194

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:11
User entered 'Yes (Y)'	Azure Erskine (b) (4)	19 Aug 2020 15:25:27
	(b) (4)	



US3152194

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:11
User entered '14 Aug 2020'	Azure Erskine (b) (4)	19 Aug 2020 15:25:27
	(b) (4)	

US3152194

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:25
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:28:14
	(b) (4)	

US3152194

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:43

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:25
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:28:14
	(b) (4)	

US3152194

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:25
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:28:14
	(b) (4)	

US3152194

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:43

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:25
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:28:14
	(b) (4)	

US3152194

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:25
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:28:14
	(b) (4)	

US3152194

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:43

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:25
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:28:14
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:25
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:28:14
	(b) (4)	



US3152194

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:43

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:25
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:28:14
	(b) (4)	

US3152194

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:35
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:28:39
	(b) (4)	

US3152194

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:35
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 13:18:28
User entered '14 Aug 2020' reason for change: Data Entry Error	Azure Erskine (b) (4)	16 Sep 2020 13:18:28
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 14:28:39
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:28:39
	(b) (4)	

US3152194

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:35
User entered 'Urine (URINE)'	Azure Erskine (b) (4)	21 Aug 2020 14:28:39
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:35
User entered 'Negative (NEGATIVE)'	Azure Erskine (b) (4)	21 Aug 2020 14:28:39
	(b) (4)	

US3152194

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:35
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update according.' (Site from DM).		29 Sep 2020 16:26:54
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update according.' answered with 'Updated to "No" regarding collection.' (Site from DM).	Azure Erskine (b) (4)	16 Sep 2020 13:19:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	16 Sep 2020 13:18:43
User entered empty; reason for change Data Entry Error	Azure Erskine (b) (4)	16 Sep 2020 13:18:33
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update according.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 07:40:52
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:28:39

**US3152194**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:35
User entered empty; reason for change Data Entry Error	Azure Erskine (b) (4)	16 Sep 2020 13:18:28
	(b) (4)	
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:28:39
	(b) (4)	

**US3152194**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:35
User entered empty; reason for change Data Entry Error	Azure Erskine (b) (4)	16 Sep 2020 13:18:28
	(b) (4)	
User entered '9:15'	Azure Erskine (b) (4)	21 Aug 2020 14:28:39
	(b) (4)	



**US3152194**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered empty.	System	16 Sep 2020 13:18:28
User entered '14 Aug 2020 9:15'	System	21 Aug 2020 14:28:39

US3152194

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

US3152194

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

US3152194

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

US3152194

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

US3152194

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	



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Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered 'I'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:07:50
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:29:22
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:15
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:15
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:29:38
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:43

[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 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:15
User entered 'Clinic (Clinic)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:38
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'VISIT1'	System	21 Aug 2020 14:29:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:29
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:54:39

US3152194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:43

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:29
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:26:01
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:26:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 13:54:39
User entered '104261' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:54:39

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:29
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 13:54:39

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:29:43**

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)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:29
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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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)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:29
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:48
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:29
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:48
	(b) (4)	



**US3152194**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:29:43**

**Diabetes (Type I, Type 2, or gestational)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:29
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:08:29
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:29:48
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:43

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'No (N)'	Priscilla Buahin (b) (4)	27 Oct 2020 16:56:47
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:13:10

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User closed query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM).		15 Sep 2020 13:06:36
Query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 14:05:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:26
User opened query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 15:15:59
User entered '170.1' cm	Azure Erskine (b) (4)	21 Aug 2020 14:35:38

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:26
	(b) (4)	
User entered '65.9' kg	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User closed query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM).		15 Sep 2020 13:06:36
Query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 14:05:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:26
User opened query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 15:15:59
User entered '170.1' cm	Azure Erskine (b) (4)	21 Aug 2020 14:35:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:26
	(b) (4)	
User entered '65.9' kg	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User accepted default value 'Pre-Dose (PREDOSE)'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '8:49'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '14 Aug 2020 8:49'	System	21 Aug 2020 14:35:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '36.6' C	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered 'Oral (Oral)'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '53'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	



**US3152194**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'bpm'	System	21 Aug 2020 14:35:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '14'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'breaths/min'	System	21 Aug 2020 14:35:38

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '129'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'mmHg'	System	21 Aug 2020 14:35:38

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '85'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'mmHg'	System	21 Aug 2020 14:35:38

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User closed query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM).		15 Sep 2020 13:06:36
Query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 14:05:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:26
User opened query 'Per CDM: Height and Weight to be recorded as ND per CCGs pages 15-16. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 15:15:59
User entered '170.1' cm	Azure Erskine (b) (4)	21 Aug 2020 14:35:38



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:26
	(b) (4)	
User entered '65.9' kg	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User accepted default value 'Post-Dose (POSTDOSE)'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '10:59'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '14 Aug 2020 10:59'	System	21 Aug 2020 14:35:38

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '98.2' F	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered 'Oral (Oral)'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '50'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'bpm'	System	21 Aug 2020 14:35:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '16'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'breaths/min'	System	21 Aug 2020 14:35:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '137'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'mmHg'	System	21 Aug 2020 14:35:38

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:09:42
User entered '79'	Azure Erskine (b) (4)	21 Aug 2020 14:35:38
	(b) (4)	



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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'mmHg'	System	21 Aug 2020 14:35:38

US3152194

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:10:44
User entered 'No (N)' reason for change: Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:37
	(b) (4)	
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:30:09
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:10:44
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:37
	(b) (4)	
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:30:09
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:10:51
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank to avoid duplication of data. Thank you. ' (Site from DM).		15 Sep 2020 19:46:55
Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank to avoid duplication of data. Thank you. ' answered with 'done' (Site from DM).	Juliana DeVito (b) (4)	12 Sep 2020 14:06:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Sep 2020 14:05:55
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank to avoid duplication of data. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 13:15:30
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:30:37

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:10:51
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:55
	(b) (4)	
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:30:37
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:10:51
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:55
	(b) (4)	
User entered 'Urine (URINE)'	Azure Erskine (b) (4)	21 Aug 2020 14:30:37
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:10:51
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:55
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Azure Erskine (b) (4)	21 Aug 2020 14:30:37
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:29:43

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:10:51
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:55
	(b) (4)	
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:30:37
	(b) (4)	



**US3152194**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:10:51
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:55
	(b) (4)	
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:30:37
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:10:51
User entered empty; reason for change Data Entry Error	Juliana DeVito (b) (4)	12 Sep 2020 14:05:55
	(b) (4)	
User entered '09:15'	Azure Erskine (b) (4)	21 Aug 2020 14:30:37
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered empty.	System	12 Sep 2020 14:05:55
User entered '14 Aug 2020 09:15'	System	21 Aug 2020 14:30:37

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:11:08
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:11:08
User entered empty.	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:11:08
User entered empty.	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:56
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 14:35:56

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:11:08
User entered '14 Aug 2020'	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:56
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:11:08
User entered '10:25'	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:56
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '14 Aug 2020 10:25'	System	14 Aug 2020 14:35:56

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:11:08
User entered 'Left Arm (LEFT ARM)'	Jemario Blackwell (b) (4)	14 Aug 2020 14:35:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
DataPoint Verified.		27 Oct 2020 14:11:08
User entered 'ONCE'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 14:35:56

US3152194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:11:59
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:31:59
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:11:59
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:31:59
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:43

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:11:59
User entered '8:59'	Azure Erskine (b) (4)	21 Aug 2020 14:31:59
	(b) (4)	



**US3152194**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '14 Aug 2020 8:59'	System	21 Aug 2020 14:31:59

US3152194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:29:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:07
User entered '14 Aug 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:31:26
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Azure Erskine (b) (4)	21 Aug 2020 14:31:26
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:07
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:31:26
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:07
User entered '9:35'	Azure Erskine (b) (4)	21 Aug 2020 14:31:26
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '14 Aug 2020 9:35'	System	21 Aug 2020 14:31:26

US3152194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Azure Erskine (b) (4)	21 Aug 2020 14:31:26
	(b) (4)	

US3152194

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:07
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:31:26
	(b) (4)	



**US3152194**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:07
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:31:26
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered empty.	System	21 Aug 2020 14:31:26

US3152194

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:12
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:32:03
	(b) (4)	

**US3152194**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered '1'	System	21 Aug 2020 14:32:03

**US3152194**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:00:12', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '405915e3-e695-42df-9671-c58e96e29140' User entered 'Yes (Y)'	System	14 Aug 2020 15:00:35
	System	14 Aug 2020 15:00:35

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:00:17', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '405915e3-e695-42df-9671-c58e96e29140' User entered '98.2'	System	14 Aug 2020 15:00:35
	System	14 Aug 2020 15:00:35

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:00:23', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '405915e3-e695-42df-9671-c58e96e29140'	System	14 Aug 2020 15:00:35
User entered 'No (N)'	System	14 Aug 2020 15:00:35



**US3152194**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:00:32', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '405915e3-e695-42df-9671-c58e96e29140'	System	14 Aug 2020 15:00:35
User entered '14 Aug 2020 11:00'	System	14 Aug 2020 15:00:35

**US3152194**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Aug 2020 10:45'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Aug 2020 13:15'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:09', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '46ac59b0-195c-4515-8ca8-b9156d328e98' User entered 'Yes (Y)'	System	14 Aug 2020 21:21:38
	System	14 Aug 2020 21:21:38

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:14', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '46ac59b0-195c-4515-8ca8-b9156d328e98' User entered '97.7'	System	14 Aug 2020 21:21:38
	System	14 Aug 2020 21:21:38

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:25', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '46ac59b0-195c-4515-8ca8-b9156d328e98'	System	14 Aug 2020 21:21:38
User entered 'No (N)'	System	14 Aug 2020 21:21:38

**US3152194**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:34', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '46ac59b0-195c-4515-8ca8-b9156d328e98' User entered '14 Aug 2020 17:21'	System	14 Aug 2020 21:21:38
	System	14 Aug 2020 21:21:38



**US3152194**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Aug 2020 14:10'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 2'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:45:27', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a0e8a6cc-0731-4b7f-9732-76bdac86a660' User entered 'Yes (Y)'	System	15 Aug 2020 19:46:00
	System	15 Aug 2020 19:46:00

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:45:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a0e8a6cc-0731-4b7f-9732-76bdac86a660' User entered '97.4'	System	15 Aug 2020 19:46:00
	System	15 Aug 2020 19:46:00

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:45:39', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a0e8a6cc-0731-4b7f-9732-76bdac86a660'	System	15 Aug 2020 19:46:00
User entered 'No (N)'	System	15 Aug 2020 19:46:00

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:45:58', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a0e8a6cc-0731-4b7f-9732-76bdac86a660' User entered '15 Aug 2020 15:45'	System	15 Aug 2020 19:46:00
	System	15 Aug 2020 19:46:00

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 14:35:56



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 3'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T17:59:58', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '58e2281c-058c-4096-8dbb-939873df36be' User entered 'Yes (Y)'	System	16 Aug 2020 22:00:15
	System	16 Aug 2020 22:00:15

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:03', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '58e2281c-058c-4096-8dbb-939873df36be' User entered '96.4'	System	16 Aug 2020 22:00:15
	System	16 Aug 2020 22:00:15

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:07', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '58e2281c-058c-4096-8dbb-939873df36be' User entered 'No (N)'	System	16 Aug 2020 22:00:15
	System	16 Aug 2020 22:00:15

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:10', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '58e2281c-058c-4096-8dbb-939873df36be' User entered '16 Aug 2020 18:00'	System	16 Aug 2020 22:00:15
	System	16 Aug 2020 22:00:15

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 14:35:56



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 4'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:03', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '8777405e-78f2-4eff-88fd-ff621c63af4a'	System	17 Aug 2020 22:58:17
User entered 'Yes (Y)'	System	17 Aug 2020 22:58:17

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:08', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '8777405e-78f2-4eff-88fd-ff621c63af4a' User entered '97.4'	System	17 Aug 2020 22:58:17
	System	17 Aug 2020 22:58:17

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:11', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '8777405e-78f2-4eff-88fd-ff621c63af4a'	System	17 Aug 2020 22:58:17
User entered 'No (N)'	System	17 Aug 2020 22:58:17

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:14', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '8777405e-78f2-4eff-88fd-ff621c63af4a'	System	17 Aug 2020 22:58:17
User entered '17 Aug 2020 18:58'	System	17 Aug 2020 22:58:17

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 5'	System	14 Aug 2020 14:35:56



US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:14:45', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '6662b7b4-ee1d-4d70-9c93-667f7459d53a' User entered 'Yes (Y)'	System	18 Aug 2020 21:14:59
	System	18 Aug 2020 21:14:59

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:14:49', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '6662b7b4-ee1d-4d70-9c93-667f7459d53a' User entered '97.5'	System	18 Aug 2020 21:14:59
	System	18 Aug 2020 21:14:59

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:14:52', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '6662b7b4-ee1d-4d70-9c93-667f7459d53a' User entered 'No (N)'	System	18 Aug 2020 21:14:59
	System	18 Aug 2020 21:14:59

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:14:56', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '6662b7b4-ee1d-4d70-9c93-667f7459d53a' User entered '18 Aug 2020 17:14'	System	18 Aug 2020 21:14:59
	System	18 Aug 2020 21:14:59

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 6'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:14', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '34c6bf18-ae13-492a-8b81-eae59baef79c' User entered 'Yes (Y)'	System	19 Aug 2020 16:00:32
	System	19 Aug 2020 16:00:32



US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:19', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '34c6bf18-ae13-492a-8b81-eae59baef79c' User entered '97.6'	System	19 Aug 2020 16:00:32
	System	19 Aug 2020 16:00:32

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:22', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '34c6bf18-ae13-492a-8b81-eae59baef79c'	System	19 Aug 2020 16:00:32
User entered 'No (N)'	System	19 Aug 2020 16:00:32

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:24', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '34c6bf18-ae13-492a-8b81-eae59baef79c' User entered '19 Aug 2020 12:00'	System	19 Aug 2020 16:00:32
	System	19 Aug 2020 16:00:32

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 7'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:12', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '87da4661-0ae8-4af3-a1b6-c4ce1302178b' User entered 'Yes (Y)'	System	20 Aug 2020 16:06:25
	System	20 Aug 2020 16:06:25

US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:16', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '87da4661-0ae8-4af3-a1b6-c4ce1302178b' User entered '97.4'	System	20 Aug 2020 16:06:25
	System	20 Aug 2020 16:06:25



US3152194

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:18', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '87da4661-0ae8-4af3-a1b6-c4ce1302178b'	System	20 Aug 2020 16:06:25
User entered 'No (N)'	System	20 Aug 2020 16:06:25

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:20', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '87da4661-0ae8-4af3-a1b6-c4ce1302178b' User entered '20 Aug 2020 12:06'	System	20 Aug 2020 16:06:25
	System	20 Aug 2020 16:06:25

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:01:58', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '026320bc-4651-4f07-afbd-36668fe74dc8' User entered 'None (1)'	System	14 Aug 2020 15:02:29
	System	14 Aug 2020 15:02:29

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:01', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '026320bc-4651-4f07-afbd-36668fe74dc8' User entered 'No (N)'	System	14 Aug 2020 15:02:29
	System	14 Aug 2020 15:02:29

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:05', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '026320bc-4651-4f07-afbd-36668fe74dc8' User entered 'No (N)'	System	14 Aug 2020 15:02:29
	System	14 Aug 2020 15:02:29



US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:20', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '026320bc-4651-4f07-afbd-36668fe74dc8' User entered 'None (1)'	System	14 Aug 2020 15:02:29
	System	14 Aug 2020 15:02:29

**US3152194**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:25', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '026320bc-4651-4f07-afbd-36668fe74dc8' User entered '14 Aug 2020 11:02'	System	14 Aug 2020 15:02:29
	System	14 Aug 2020 15:02:29

**US3152194**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Aug 2020 10:45'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Aug 2020 13:15'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:40', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3213032d-dff0-4af2-a283-fa769128a14a' User entered 'None (1)'	System	14 Aug 2020 21:21:55
	System	14 Aug 2020 21:21:55

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:44', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3213032d-dff0-4af2-a283-fa769128a14a' User entered 'No (N)'	System	14 Aug 2020 21:21:55
	System	14 Aug 2020 21:21:55

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:47', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3213032d-dff0-4af2-a283-fa769128a14a' User entered 'No (N)'	System	14 Aug 2020 21:21:55
	System	14 Aug 2020 21:21:55



US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:50', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3213032d-dff0-4af2-a283-fa769128a14a' User entered 'None (1)'	System	14 Aug 2020 21:21:55
	System	14 Aug 2020 21:21:55

**US3152194**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:52', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3213032d-dff0-4af2-a283-fa769128a14a' User entered '14 Aug 2020 17:21'	System	14 Aug 2020 21:21:55
	System	14 Aug 2020 21:21:55

**US3152194**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Aug 2020 14:10'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 2'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:03', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dbd795e0-a296-4ce3-8e76-e4a1dd1d5d44'	System	15 Aug 2020 19:46:21
User entered 'None (1)'	System	15 Aug 2020 19:46:21

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:06', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dbd795e0-a296-4ce3-8e76-e4a1dd1d5d44'	System	15 Aug 2020 19:46:21
User entered 'No (N)'	System	15 Aug 2020 19:46:21

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:09', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dbd795e0-a296-4ce3-8e76-e4a1dd1d5d44'	System	15 Aug 2020 19:46:21
User entered 'No (N)'	System	15 Aug 2020 19:46:21



US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:15', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dbd795e0-a296-4ce3-8e76-e4a1dd1d5d44'	System	15 Aug 2020 19:46:21
User entered 'None (1)'	System	15 Aug 2020 19:46:21

**US3152194**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:19', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dbd795e0-a296-4ce3-8e76-e4a1dd1d5d44' User entered '15 Aug 2020 15:46'	System	15 Aug 2020 19:46:21
	System	15 Aug 2020 19:46:21

**US3152194**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 3'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:14', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'ea4a33ac-430d-453d-a321-ed1582e5f1ef' User entered 'None (1)'	System	16 Aug 2020 22:00:31
	System	16 Aug 2020 22:00:31

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:17', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'ea4a33ac-430d-453d-a321-ed1582e5f1ef' User entered 'No (N)'	System	16 Aug 2020 22:00:31
	System	16 Aug 2020 22:00:31

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:19', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'ea4a33ac-430d-453d-a321-ed1582e5f1ef' User entered 'No (N)'	System	16 Aug 2020 22:00:31
	System	16 Aug 2020 22:00:31



US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:24', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'ea4a33ac-430d-453d-a321-ed1582e5f1ef' User entered 'None (1)'	System	16 Aug 2020 22:00:31
	System	16 Aug 2020 22:00:31

**US3152194**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:26', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'ea4a33ac-430d-453d-a321-ed1582e5f1ef' User entered '16 Aug 2020 18:00'	System	16 Aug 2020 22:00:31
	System	16 Aug 2020 22:00:31

**US3152194**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 4'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:19', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a56c58a9-b810-4235-99ef-256a821cf3ad'	System	17 Aug 2020 22:58:32
User entered 'None (1)'	System	17 Aug 2020 22:58:32

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:21', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a56c58a9-b810-4235-99ef-256a821cf3ad'	System	17 Aug 2020 22:58:32
User entered 'No (N)'	System	17 Aug 2020 22:58:32

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:24', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a56c58a9-b810-4235-99ef-256a821cf3ad' User entered 'No (N)'	System	17 Aug 2020 22:58:32
	System	17 Aug 2020 22:58:32



US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:27', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a56c58a9-b810-4235-99ef-256a821cf3ad'	System	17 Aug 2020 22:58:32
User entered 'None (1)'	System	17 Aug 2020 22:58:32

**US3152194**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:30', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a56c58a9-b810-4235-99ef-256a821cf3ad' User entered '17 Aug 2020 18:58'	System	17 Aug 2020 22:58:32
	System	17 Aug 2020 22:58:32

**US3152194**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 5'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:00', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '37ad9b74-90d0-4b54-9f50-d4282034788f' User entered 'None (1)'	System	18 Aug 2020 21:15:15
	System	18 Aug 2020 21:15:15

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:03', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '37ad9b74-90d0-4b54-9f50-d4282034788f' User entered 'No (N)'	System	18 Aug 2020 21:15:15
	System	18 Aug 2020 21:15:15

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:05', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '37ad9b74-90d0-4b54-9f50-d4282034788f' User entered 'No (N)'	System	18 Aug 2020 21:15:15
	System	18 Aug 2020 21:15:15



US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:08', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '37ad9b74-90d0-4b54-9f50-d4282034788f' User entered 'None (1)'	System	18 Aug 2020 21:15:15
	System	18 Aug 2020 21:15:15

**US3152194**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:10', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '37ad9b74-90d0-4b54-9f50-d4282034788f' User entered '18 Aug 2020 17:15'	System	18 Aug 2020 21:15:15
	System	18 Aug 2020 21:15:15

**US3152194**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 6'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:28', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'efa076d4-9c96-44a2-b225-32fdb95324e1' User entered 'None (1)'	System	19 Aug 2020 16:00:48
	System	19 Aug 2020 16:00:48

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:30', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'efa076d4-9c96-44a2-b225-32fdb95324e1' User entered 'No (N)'	System	19 Aug 2020 16:00:48
	System	19 Aug 2020 16:00:48

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:33', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'efa076d4-9c96-44a2-b225-32fdb95324e1' User entered 'No (N)'	System	19 Aug 2020 16:00:48
	System	19 Aug 2020 16:00:48



US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'efa076d4-9c96-44a2-b225-32fdb95324e1' User entered 'None (1)'	System	19 Aug 2020 16:00:48
	System	19 Aug 2020 16:00:48

**US3152194**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:37', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'efa076d4-9c96-44a2-b225-32fdb95324e1' User entered '19 Aug 2020 12:00'	System	19 Aug 2020 16:00:48
	System	19 Aug 2020 16:00:48

**US3152194**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 7'	System	14 Aug 2020 14:35:56

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:24', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'aaab1ca3-a1d8-40a4-9b34-bf03dcf2e38a' User entered 'None (1)'	System	20 Aug 2020 16:06:37
	System	20 Aug 2020 16:06:37

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:26', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'aaab1ca3-a1d8-40a4-9b34-bf03dcf2e38a' User entered 'No (N)'	System	20 Aug 2020 16:06:37
	System	20 Aug 2020 16:06:37

US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:29', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'aaab1ca3-a1d8-40a4-9b34-bf03dcf2e38a' User entered 'No (N)'	System	20 Aug 2020 16:06:37
	System	20 Aug 2020 16:06:37



US3152194

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:31', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'aaab1ca3-a1d8-40a4-9b34-bf03dcf2e38a' User entered 'None (1)'	System	20 Aug 2020 16:06:37
	System	20 Aug 2020 16:06:37

**US3152194**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:33', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'aaab1ca3-a1d8-40a4-9b34-bf03dcf2e38a' User entered '20 Aug 2020 12:06'	System	20 Aug 2020 16:06:37
	System	20 Aug 2020 16:06:37

**US3152194**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:32', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '16ece396-622f-43a4-bda2-bc4c26fdcc45' User entered 'None (0)'	System	14 Aug 2020 15:03:03
	System	14 Aug 2020 15:03:03

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '16ece396-622f-43a4-bda2-bc4c26fdcc45' User entered 'None (0)'	System	14 Aug 2020 15:03:03
	System	14 Aug 2020 15:03:03

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:38', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '16ece396-622f-43a4-bda2-bc4c26fdcc45' User entered 'None (0)'	System	14 Aug 2020 15:03:03
	System	14 Aug 2020 15:03:03



US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:41', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '16ece396-622f-43a4-bda2-bc4c26fdcc45' User entered 'None (0)'	System	14 Aug 2020 15:03:03
	System	14 Aug 2020 15:03:03

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:43', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '16ece396-622f-43a4-bda2-bc4c26fdcc45' User entered 'None (0)'	System	14 Aug 2020 15:03:03
	System	14 Aug 2020 15:03:03

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:45', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '16ece396-622f-43a4-bda2-bc4c26fdcc45' User entered 'None (0)'	System	14 Aug 2020 15:03:03
	System	14 Aug 2020 15:03:03

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:49', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '16ece396-622f-43a4-bda2-bc4c26fdcc45'	System	14 Aug 2020 15:03:03
User entered 'No (N)'	System	14 Aug 2020 15:03:03

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T11:02:52', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '16ece396-622f-43a4-bda2-bc4c26fdcc45' User entered '14 Aug 2020 11:02'	System	14 Aug 2020 15:03:03
	System	14 Aug 2020 15:03:03

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Aug 2020 10:45'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Aug 2020 13:15'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 14:35:56



US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:21:58', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c82924de-49de-4c90-83f0-50fa9e5f68ab' User entered 'None (0)'	System	14 Aug 2020 21:22:39
	System	14 Aug 2020 21:22:39

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:22:01', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c82924de-49de-4c90-83f0-50fa9e5f68ab' User entered 'None (0)'	System	14 Aug 2020 21:22:39
	System	14 Aug 2020 21:22:39

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:22:05', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c82924de-49de-4c90-83f0-50fa9e5f68ab' User entered 'None (0)'	System	14 Aug 2020 21:22:39
	System	14 Aug 2020 21:22:39

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:22:09', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c82924de-49de-4c90-83f0-50fa9e5f68ab' User entered 'None (0)'	System	14 Aug 2020 21:22:39
	System	14 Aug 2020 21:22:39

**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:22:12', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c82924de-49de-4c90-83f0-50fa9e5f68ab' User entered 'None (0)'	System	14 Aug 2020 21:22:39
	System	14 Aug 2020 21:22:39

**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:22:15', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c82924de-49de-4c90-83f0-50fa9e5f68ab' User entered 'None (0)'	System	14 Aug 2020 21:22:39
	System	14 Aug 2020 21:22:39

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:22:20', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c82924de-49de-4c90-83f0-50fa9e5f68ab' User entered 'No (N)'	System	14 Aug 2020 21:22:39
	System	14 Aug 2020 21:22:39

**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-14T17:22:37', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c82924de-49de-4c90-83f0-50fa9e5f68ab' User entered '14 Aug 2020 17:22'	System	14 Aug 2020 21:22:39
	System	14 Aug 2020 21:22:39



**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Aug 2020 14:10'	System	14 Aug 2020 14:35:56

**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 2'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:25', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '26582294-e1bf-43a2-a954-8f15143cd740' User entered 'None (0)'	System	15 Aug 2020 19:46:58
	System	15 Aug 2020 19:46:58

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:28', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '26582294-e1bf-43a2-a954-8f15143cd740' User entered 'None (0)'	System	15 Aug 2020 19:46:58
	System	15 Aug 2020 19:46:58

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:32', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '26582294-e1bf-43a2-a954-8f15143cd740' User entered 'None (0)'	System	15 Aug 2020 19:46:58
	System	15 Aug 2020 19:46:58

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '26582294-e1bf-43a2-a954-8f15143cd740' User entered 'None (0)'	System	15 Aug 2020 19:46:58
	System	15 Aug 2020 19:46:58

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:38', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '26582294-e1bf-43a2-a954-8f15143cd740' User entered 'None (0)'	System	15 Aug 2020 19:46:58
	System	15 Aug 2020 19:46:58



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:43', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '26582294-e1bf-43a2-a954-8f15143cd740' User entered 'None (0)'	System	15 Aug 2020 19:46:58
	System	15 Aug 2020 19:46:58

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:48', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '26582294-e1bf-43a2-a954-8f15143cd740' User entered 'No (N)'	System	15 Aug 2020 19:46:58
	System	15 Aug 2020 19:46:58

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-15T15:46:55', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '26582294-e1bf-43a2-a954-8f15143cd740'	System	15 Aug 2020 19:46:58
User entered '15 Aug 2020 15:46'	System	15 Aug 2020 19:46:58

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 3'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:31', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '7e04e140-4eed-49ef-9047-ba70ce0bf739' User entered 'None (0)'	System	16 Aug 2020 22:01:00
	System	16 Aug 2020 22:01:00

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '7e04e140-4eed-49ef-9047-ba70ce0bf739' User entered 'None (0)'	System	16 Aug 2020 22:01:00
	System	16 Aug 2020 22:01:00



US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:37', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '7e04e140-4eed-49ef-9047-ba70ce0bf739' User entered 'None (0)'	System	16 Aug 2020 22:01:00
	System	16 Aug 2020 22:01:00

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:40', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '7e04e140-4eed-49ef-9047-ba70ce0bf739' User entered 'None (0)'	System	16 Aug 2020 22:01:00
	System	16 Aug 2020 22:01:00

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:45', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '7e04e140-4eed-49ef-9047-ba70ce0bf739' User entered 'None (0)'	System	16 Aug 2020 22:01:00
	System	16 Aug 2020 22:01:00

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:51', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '7e04e140-4eed-49ef-9047-ba70ce0bf739' User entered 'None (0)'	System	16 Aug 2020 22:01:00
	System	16 Aug 2020 22:01:00

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:56', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '7e04e140-4eed-49ef-9047-ba70ce0bf739'	System	16 Aug 2020 22:01:00
User entered 'No (N)'	System	16 Aug 2020 22:01:00

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-16T18:00:59', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '7e04e140-4eed-49ef-9047-ba70ce0bf739'	System	16 Aug 2020 22:01:00
User entered '16 Aug 2020 18:00'	System	16 Aug 2020 22:01:00

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 14:35:56



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 4'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:33', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '27c6d20d-8532-4238-bf26-8fa3ae99fcd6' User entered 'None (0)'	System	17 Aug 2020 22:58:56
	System	17 Aug 2020 22:58:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '27c6d20d-8532-4238-bf26-8fa3ae99fcd6' User entered 'None (0)'	System	17 Aug 2020 22:58:56
	System	17 Aug 2020 22:58:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:39', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '27c6d20d-8532-4238-bf26-8fa3ae99fcd6' User entered 'None (0)'	System	17 Aug 2020 22:58:56
	System	17 Aug 2020 22:58:56

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:41', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '27c6d20d-8532-4238-bf26-8fa3ae99fcd6' User entered 'None (0)'	System	17 Aug 2020 22:58:56
	System	17 Aug 2020 22:58:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:43', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '27c6d20d-8532-4238-bf26-8fa3ae99fcd6' User entered 'None (0)'	System	17 Aug 2020 22:58:56
	System	17 Aug 2020 22:58:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:46', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '27c6d20d-8532-4238-bf26-8fa3ae99fcd6' User entered 'None (0)'	System	17 Aug 2020 22:58:56
	System	17 Aug 2020 22:58:56

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:50', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '27c6d20d-8532-4238-bf26-8fa3ae99fcd6'	System	17 Aug 2020 22:58:56
User entered 'No (N)'	System	17 Aug 2020 22:58:56



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-17T18:58:53', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '27c6d20d-8532-4238-bf26-8fa3ae99fcd6' User entered '17 Aug 2020 18:58'	System	17 Aug 2020 22:58:56
	System	17 Aug 2020 22:58:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 5'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:13', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a613a5fa-ff78-48b3-bd41-c094a46cb962'	System	18 Aug 2020 21:15:33
User entered 'None (0)'	System	18 Aug 2020 21:15:33

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:16', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a613a5fa-ff78-48b3-bd41-c094a46cb962'	System	18 Aug 2020 21:15:33
User entered 'None (0)'	System	18 Aug 2020 21:15:33

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:18', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a613a5fa-ff78-48b3-bd41-c094a46cb962'	System	18 Aug 2020 21:15:33
User entered 'None (0)'	System	18 Aug 2020 21:15:33

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:20', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a613a5fa-ff78-48b3-bd41-c094a46cb962'	System	18 Aug 2020 21:15:33
User entered 'None (0)'	System	18 Aug 2020 21:15:33



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:22', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a613a5fa-ff78-48b3-bd41-c094a46cb962'	System	18 Aug 2020 21:15:33
User entered 'None (0)'	System	18 Aug 2020 21:15:33

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:24', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a613a5fa-ff78-48b3-bd41-c094a46cb962'	System	18 Aug 2020 21:15:33
User entered 'None (0)'	System	18 Aug 2020 21:15:33

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:29', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a613a5fa-ff78-48b3-bd41-c094a46cb962'	System	18 Aug 2020 21:15:33
User entered 'No (N)'	System	18 Aug 2020 21:15:33

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-18T17:15:31', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a613a5fa-ff78-48b3-bd41-c094a46cb962'	System	18 Aug 2020 21:15:33
User entered '18 Aug 2020 17:15'	System	18 Aug 2020 21:15:33

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 6'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:41', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dc1d24c4-7805-4659-8d5c-9416bf29ace1' User entered 'None (0)'	System	19 Aug 2020 16:01:12
	System	19 Aug 2020 16:01:12



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:43', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dc1d24c4-7805-4659-8d5c-9416bf29ace1' User entered 'None (0)'	System	19 Aug 2020 16:01:12
	System	19 Aug 2020 16:01:12

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:45', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dc1d24c4-7805-4659-8d5c-9416bf29ace1' User entered 'None (0)'	System	19 Aug 2020 16:01:12
	System	19 Aug 2020 16:01:12

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:47', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dc1d24c4-7805-4659-8d5c-9416bf29ace1' User entered 'None (0)'	System	19 Aug 2020 16:01:12
	System	19 Aug 2020 16:01:12

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:49', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dc1d24c4-7805-4659-8d5c-9416bf29ace1' User entered 'None (0)'	System	19 Aug 2020 16:01:12
	System	19 Aug 2020 16:01:12

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:52', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dc1d24c4-7805-4659-8d5c-9416bf29ace1' User entered 'None (0)'	System	19 Aug 2020 16:01:12
	System	19 Aug 2020 16:01:12

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:55', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dc1d24c4-7805-4659-8d5c-9416bf29ace1' User entered 'No (N)'	System	19 Aug 2020 16:01:12
	System	19 Aug 2020 16:01:12

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-19T12:00:57', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'dc1d24c4-7805-4659-8d5c-9416bf29ace1' User entered '19 Aug 2020 12:00'	System	19 Aug 2020 16:01:12
	System	19 Aug 2020 16:01:12

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 14:35:56



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 7'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:36', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '020c0b50-afe3-48f9-9ecf-9769a351dd97'	System	21 Aug 2020 18:57:28
User entered 'None (0)'	System	21 Aug 2020 18:57:28

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:38', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '020c0b50-afe3-48f9-9ecf-9769a351dd97'	System	21 Aug 2020 18:57:28
User entered 'None (0)'	System	21 Aug 2020 18:57:28

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:40', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '020c0b50-afe3-48f9-9ecf-9769a351dd97'	System	21 Aug 2020 18:57:28
User entered 'None (0)'	System	21 Aug 2020 18:57:28

US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:43', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '020c0b50-afe3-48f9-9ecf-9769a351dd97'	System	21 Aug 2020 18:57:28
User entered 'None (0)'	System	21 Aug 2020 18:57:28

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:44', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '020c0b50-afe3-48f9-9ecf-9769a351dd97'	System	21 Aug 2020 18:57:28
User entered 'None (0)'	System	21 Aug 2020 18:57:28

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:46', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '020c0b50-afe3-48f9-9ecf-9769a351dd97' User entered 'None (0)'	System	21 Aug 2020 18:57:28
	System	21 Aug 2020 18:57:28



US3152194

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:52', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '020c0b50-afe3-48f9-9ecf-9769a351dd97'	System	21 Aug 2020 18:57:28
User entered 'No (N)'	System	21 Aug 2020 18:57:28

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-08-20T12:06:54', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '020c0b50-afe3-48f9-9ecf-9769a351dd97'	System	21 Aug 2020 18:57:28
User entered '20 Aug 2020 12:06'	System	21 Aug 2020 18:57:28

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 14:35:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 14:35:56

US3152194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:47
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	24 Aug 2020 17:01:05
	(b) (4)	

US3152194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:47
User entered '24 Aug 2020'	Jemario Blackwell (b) (4)	24 Aug 2020 17:01:05
	(b) (4)	

US3152194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:47
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	24 Aug 2020 17:01:05

US3152194

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:12:47
User entered empty.	Jemario Blackwell (b) (4)	24 Aug 2020 17:01:05
	(b) (4)	



US3152194

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:13:49
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	24 Aug 2020 17:01:11
	(b) (4)	

**US3152194**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'I'	System	24 Aug 2020 17:01:11

US3152194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:13:56
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:04
	(b) (4)	

US3152194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:13:56
User entered '28 Aug 2020'	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:04
	(b) (4)	

US3152194

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:13:56
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:04
	(b) (4)	

**US3152194**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:13:56
User entered empty.	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:04
	(b) (4)	

US3152194

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:14:01
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:08
	(b) (4)	

**US3152194**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:40:13
User entered 'I'	System	09 Sep 2020 15:45:08



US3152194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:47:40
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 11SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:20:34
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 11SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Visit 2 Day 29 completed on 11Sep2020. EDC completed for the visit.' (Site from DM).	Priscilla Buahin (b) (4)	28 Oct 2020 14:51:40
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:16:04
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 11SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		21 Oct 2020 10:01:15
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:31

US3152194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:47:40
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:20:59
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Visit 2 Day 29 completed on 11Sep2020. EDC completed for the visit.' (Site from DM).	Priscilla Buahin (b) (4)	28 Oct 2020 14:51:44
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:16:04
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:45:55
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 06:08:32

US3152194

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'tried contacting during window ' (Site from System).	Jemario Blackwell (b) (4)	14 Sep 2020 21:00:11
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 15:45:31
User entered '09 Sep 2020'	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:31

**US3152194**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:47:40
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:16:04
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:31

**US3152194**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:47:40
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:16:04
User entered empty.	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:31

**US3152194**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:47:40
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:16:13
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	09 Sep 2020 15:45:38
	(b) (4)	

**US3152194**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:47:40
User entered 'I'	System	09 Sep 2020 15:45:38

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 16:59:53



**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '11 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 16:59:53

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Clinic (Clinic)'	Priscilla Buahin (b) (4)	27 Oct 2020 16:59:53

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'VISIT2'	System	27 Oct 2020 16:59:53

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User accepted default value 'Pre-Dose (PREDOSE)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07
	(b) (4)	

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '11 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '13:23'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered '11 Sep 2020 13:23'	System	27 Oct 2020 17:03:07



US3152194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '36.7' C	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Oral (Oral)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered empty.	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '55'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'bpm'	System	27 Oct 2020 17:03:07

US3152194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '14'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'breaths/min'	System	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '148'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07



**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'mmHg'	System	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '88'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'mmHg'	System	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User accepted default value 'Post-Dose (POSTDOSE)'	Priscilla Buahin (b) (4) (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

US3152194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '11 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '15:01'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered '11 Sep 2020 15:01'	System	27 Oct 2020 17:03:07



US3152194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '36.6' C	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Oral (Oral)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered empty.	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '53'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'bpm'	System	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '14'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'breaths/min'	System	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '150'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07



**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'mmHg'	System	27 Oct 2020 17:03:07

US3152194

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '88'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'mmHg'	System	27 Oct 2020 17:03:07

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:43**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:32

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:43**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '11 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:32

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:55

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '11 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:55

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Urine (URINE)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:55



**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Negative (NEGATIVE)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:55

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'No (N)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:55

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered empty.	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:55

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered empty.	Priscilla Buahin (b) (4)	27 Oct 2020 17:03:55

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered empty.	System	27 Oct 2020 17:03:55

US3152194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 11 SEP 2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:48:18
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 11 SEP 2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:21:27
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 17SEP2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:20:44
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 17SEP2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:20:39
User entered 'Yes (Y)'	Devan Myers (b) (4) (b) (4)	11 Sep 2020 18:35:37

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered empty.	Devan Myers (b) (4)	11 Sep 2020 18:35:37

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered empty.	Devan Myers (b) (4)	11 Sep 2020 18:35:37



**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 18:35:37

US3152194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '11 Sep 2020'	Devan Myers (b) (4)	11 Sep 2020 18:35:37

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '14:31'	Devan Myers (b) (4)	11 Sep 2020 18:35:37

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered '11 Sep 2020 14:31'	System	11 Sep 2020 18:35:37

US3152194

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Left Arm (LEFT ARM)'	Devan Myers (b) (4)	11 Sep 2020 18:35:37

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'ONCE'	System	11 Sep 2020 18:35:37

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 18:35:37

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:24



**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '11 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:24

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '13:41'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:24

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered '11 Sep 2020 13:41'	System	27 Oct 2020 17:04:24

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 15:29:43**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '11 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:49

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:49

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:49

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '13:36'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:49

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered '11 Sep 2020 13:36'	System	27 Oct 2020 17:04:49



**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:49

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'No (N)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:49

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered empty.	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:49

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered empty.	System	27 Oct 2020 17:04:49

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:04:54

**US3152194**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'I'	System	27 Oct 2020 17:04:54

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:02:36', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4080f62e-ad3b-4490-9960-2449d2a94365' User entered 'Yes (Y)'	System	11 Sep 2020 19:02:59
	System	11 Sep 2020 19:02:59



US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:02:46', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4080f62e-ad3b-4490-9960-2449d2a94365' User entered '97.9'	System	11 Sep 2020 19:02:59
	System	11 Sep 2020 19:02:59

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:02:50', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4080f62e-ad3b-4490-9960-2449d2a94365' User entered 'No (N)'	System	11 Sep 2020 19:02:59
	System	11 Sep 2020 19:02:59

**US3152194**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:02:54', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4080f62e-ad3b-4490-9960-2449d2a94365' User entered '11 Sep 2020 15:02'	System	11 Sep 2020 19:02:59
	System	11 Sep 2020 19:02:59

**US3152194**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '11 Sep 2020 14:51'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '11 Sep 2020 17:21'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:47:33', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '643d09ad-cd62-44e3-8716-17842d4955a1' User entered 'No (N)'	System	12 Sep 2020 02:47:43
	System	12 Sep 2020 02:47:43

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:47:36', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '643d09ad-cd62-44e3-8716-17842d4955a1'	System	12 Sep 2020 02:47:43
User entered 'No (N)'	System	12 Sep 2020 02:47:43



**US3152194**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:47:40', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '643d09ad-cd62-44e3-8716-17842d4955a1' User entered '11 Sep 2020 22:47'	System	12 Sep 2020 02:47:43
	System	12 Sep 2020 02:47:43

**US3152194**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '11 Sep 2020 18:16'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 2'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:43:53', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '78b2705f-3857-4cb2-869f-317553023a57' User entered 'Yes (Y)'	System	13 Sep 2020 01:44:04
	System	13 Sep 2020 01:44:04

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:43:58', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '78b2705f-3857-4cb2-869f-317553023a57' User entered '97.4'	System	13 Sep 2020 01:44:04
	System	13 Sep 2020 01:44:04

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:00', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '78b2705f-3857-4cb2-869f-317553023a57'	System	13 Sep 2020 01:44:04
User entered 'No (N)'	System	13 Sep 2020 01:44:04

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:03', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '78b2705f-3857-4cb2-869f-317553023a57'	System	13 Sep 2020 01:44:04
User entered '12 Sep 2020 21:44'	System	13 Sep 2020 01:44:04



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 3'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:29', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5c4f2a04-279e-4cf0-af0f-9d4d794b4b3a' User entered 'Yes (Y)'	System	13 Sep 2020 23:59:50
	System	13 Sep 2020 23:59:50

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5c4f2a04-279e-4cf0-af0f-9d4d794b4b3a' User entered '97.6'	System	13 Sep 2020 23:59:50
	System	13 Sep 2020 23:59:50

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:38', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5c4f2a04-279e-4cf0-af0f-9d4d794b4b3a' User entered 'No (N)'	System	13 Sep 2020 23:59:50
	System	13 Sep 2020 23:59:50

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:41', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5c4f2a04-279e-4cf0-af0f-9d4d794b4b3a' User entered '13 Sep 2020 19:59'	System	13 Sep 2020 23:59:50
	System	13 Sep 2020 23:59:50

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:35:37



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 4'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:14:53', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'ef454fb8-2a70-4f02-8230-4030635d08f5' User entered 'Yes (Y)'	System	15 Sep 2020 10:15:07
	System	15 Sep 2020 10:15:07

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:14:59', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'ef454fb8-2a70-4f02-8230-4030635d08f5' User entered '97.8'	System	15 Sep 2020 10:15:07
	System	15 Sep 2020 10:15:07

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:03', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'ef454fb8-2a70-4f02-8230-4030635d08f5'	System	15 Sep 2020 10:15:07
User entered 'No (N)'	System	15 Sep 2020 10:15:07

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:05', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'ef454fb8-2a70-4f02-8230-4030635d08f5' User entered '15 Sep 2020 06:15'	System	15 Sep 2020 10:15:07
	System	15 Sep 2020 10:15:07

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:35:37



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 5'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:00:50', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c7bbd4ae-67ba-444b-82ff-c17e189d8655' User entered 'Yes (Y)'	System	15 Sep 2020 16:01:56
	System	15 Sep 2020 16:01:56

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:00:54', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c7bbd4ae-67ba-444b-82ff-c17e189d8655' User entered '97.5'	System	15 Sep 2020 16:01:56
	System	15 Sep 2020 16:01:56

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:00:56', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c7bbd4ae-67ba-444b-82ff-c17e189d8655'	System	15 Sep 2020 16:01:56
User entered 'No (N)'	System	15 Sep 2020 16:01:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:00:58', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c7bbd4ae-67ba-444b-82ff-c17e189d8655' User entered '15 Sep 2020 12:00'	System	15 Sep 2020 16:01:56
	System	15 Sep 2020 16:01:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 6'	System	11 Sep 2020 18:35:37



US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:30', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '986e211d-72e1-4341-ac33-77c0d70a2f69' User entered 'Yes (Y)'	System	17 Sep 2020 11:10:42
	System	17 Sep 2020 11:10:42

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:34', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '986e211d-72e1-4341-ac33-77c0d70a2f69' User entered '98.0'	System	17 Sep 2020 11:10:42
	System	17 Sep 2020 11:10:42

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:37', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '986e211d-72e1-4341-ac33-77c0d70a2f69'	System	17 Sep 2020 11:10:42
User entered 'No (N)'	System	17 Sep 2020 11:10:42

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:39', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '986e211d-72e1-4341-ac33-77c0d70a2f69' User entered '17 Sep 2020 07:10'	System	17 Sep 2020 11:10:42
	System	17 Sep 2020 11:10:42

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 7'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:19:45', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'edd8b185-8f01-4bbb-bc97-c59a4c743652' User entered 'Yes (Y)'	System	17 Sep 2020 23:19:56
	System	17 Sep 2020 23:19:56



US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:19:49', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'edd8b185-8f01-4bbb-bc97-c59a4c743652' User entered '97.4'	System	17 Sep 2020 23:19:56
	System	17 Sep 2020 23:19:56

US3152194

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:19:51', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'edd8b185-8f01-4bbb-bc97-c59a4c743652'	System	17 Sep 2020 23:19:56
User entered 'No (N)'	System	17 Sep 2020 23:19:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:19:54', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'edd8b185-8f01-4bbb-bc97-c59a4c743652' User entered '17 Sep 2020 19:19'	System	17 Sep 2020 23:19:56
	System	17 Sep 2020 23:19:56

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:00', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'd130b70f-d857-448b-b6c6-2d2cd28504a1' User entered 'None (1)'	System	11 Sep 2020 19:03:24
	System	11 Sep 2020 19:03:24

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:03', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'd130b70f-d857-448b-b6c6-2d2cd28504a1' User entered 'No (N)'	System	11 Sep 2020 19:03:24
	System	11 Sep 2020 19:03:24



US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:05', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'd130b70f-d857-448b-b6c6-2d2cd28504a1' User entered 'No (N)'	System	11 Sep 2020 19:03:24
	System	11 Sep 2020 19:03:24

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:09', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'd130b70f-d857-448b-b6c6-2d2cd28504a1' User entered 'None (1)'	System	11 Sep 2020 19:03:24
	System	11 Sep 2020 19:03:24

**US3152194**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:11', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'd130b70f-d857-448b-b6c6-2d2cd28504a1' User entered '11 Sep 2020 15:03'	System	11 Sep 2020 19:03:24
	System	11 Sep 2020 19:03:24

**US3152194**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '11 Sep 2020 14:51'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '11 Sep 2020 17:21'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:47:44', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'db7fee36-9906-48bb-a74e-1004806147b6' User entered 'None (1)'	System	12 Sep 2020 02:47:57
	System	12 Sep 2020 02:47:57

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:47:47', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'db7fee36-9906-48bb-a74e-1004806147b6' User entered 'No (N)'	System	12 Sep 2020 02:47:57
	System	12 Sep 2020 02:47:57



US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:47:50', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'db7fee36-9906-48bb-a74e-1004806147b6' User entered 'No (N)'	System	12 Sep 2020 02:47:57
	System	12 Sep 2020 02:47:57

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:47:53', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'db7fee36-9906-48bb-a74e-1004806147b6' User entered 'None (1)'	System	12 Sep 2020 02:47:57
	System	12 Sep 2020 02:47:57

**US3152194**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:47:56', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'db7fee36-9906-48bb-a74e-1004806147b6' User entered '11 Sep 2020 22:47'	System	12 Sep 2020 02:47:57
	System	12 Sep 2020 02:47:57

**US3152194**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '11 Sep 2020 18:16'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 2'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:07', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a7d7e5af-59df-4802-a878-32fc109b1859'	System	13 Sep 2020 01:44:20
User entered 'None (1)'	System	13 Sep 2020 01:44:20

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:10', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a7d7e5af-59df-4802-a878-32fc109b1859'	System	13 Sep 2020 01:44:20
User entered 'No (N)'	System	13 Sep 2020 01:44:20



US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:13', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a7d7e5af-59df-4802-a878-32fc109b1859'	System	13 Sep 2020 01:44:20
User entered 'No (N)'	System	13 Sep 2020 01:44:20

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:15', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a7d7e5af-59df-4802-a878-32fc109b1859'	System	13 Sep 2020 01:44:20
User entered 'None (1)'	System	13 Sep 2020 01:44:20

**US3152194**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:17', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a7d7e5af-59df-4802-a878-32fc109b1859' User entered '12 Sep 2020 21:44'	System	13 Sep 2020 01:44:20
	System	13 Sep 2020 01:44:20

**US3152194**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 3'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:44', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3b3e0ac8-736a-4a69-906a-0982d862b0ed' User entered 'None (1)'	System	13 Sep 2020 23:59:55
	System	13 Sep 2020 23:59:55

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:47', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3b3e0ac8-736a-4a69-906a-0982d862b0ed' User entered 'No (N)'	System	13 Sep 2020 23:59:55
	System	13 Sep 2020 23:59:55



US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:49', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3b3e0ac8-736a-4a69-906a-0982d862b0ed' User entered 'No (N)'	System	13 Sep 2020 23:59:55
	System	13 Sep 2020 23:59:55

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:51', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3b3e0ac8-736a-4a69-906a-0982d862b0ed' User entered 'None (1)'	System	13 Sep 2020 23:59:55
	System	13 Sep 2020 23:59:55

**US3152194**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:54', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '3b3e0ac8-736a-4a69-906a-0982d862b0ed' User entered '13 Sep 2020 19:59'	System	13 Sep 2020 23:59:55
	System	13 Sep 2020 23:59:55

**US3152194**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 4'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:12', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'de35f42f-67c2-42b5-92d4-9476b76b5de8' User entered 'None (1)'	System	15 Sep 2020 10:15:24
	System	15 Sep 2020 10:15:24

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:14', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'de35f42f-67c2-42b5-92d4-9476b76b5de8' User entered 'No (N)'	System	15 Sep 2020 10:15:24
	System	15 Sep 2020 10:15:24



US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:17', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'de35f42f-67c2-42b5-92d4-9476b76b5de8' User entered 'No (N)'	System	15 Sep 2020 10:15:24
	System	15 Sep 2020 10:15:24

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:20', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'de35f42f-67c2-42b5-92d4-9476b76b5de8' User entered 'None (1)'	System	15 Sep 2020 10:15:24
	System	15 Sep 2020 10:15:24

**US3152194**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:22', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'de35f42f-67c2-42b5-92d4-9476b76b5de8' User entered '15 Sep 2020 06:15'	System	15 Sep 2020 10:15:24
	System	15 Sep 2020 10:15:24

**US3152194**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 5'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:02', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fcbfd8aa-2190-434a-a3dc-ee4557973704'	System	15 Sep 2020 16:02:22
User entered 'None (1)'	System	15 Sep 2020 16:02:22

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:05', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fcbfd8aa-2190-434a-a3dc-ee4557973704' User entered 'No (N)'	System	15 Sep 2020 16:02:22
	System	15 Sep 2020 16:02:22



US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:07', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fcbfd8aa-2190-434a-a3dc-ee4557973704'	System	15 Sep 2020 16:02:22
User entered 'No (N)'	System	15 Sep 2020 16:02:22

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:10', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fcbfd8aa-2190-434a-a3dc-ee4557973704'	System	15 Sep 2020 16:02:22
User entered 'None (1)'	System	15 Sep 2020 16:02:22

**US3152194**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:12', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fcbfd8aa-2190-434a-a3dc-ee4557973704' User entered '15 Sep 2020 12:01'	System	15 Sep 2020 16:02:22
	System	15 Sep 2020 16:02:22

**US3152194**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 6'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:43', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a022bb05-fb1b-4c11-9d52-58fe52ccfb09'	System	17 Sep 2020 11:10:58
User entered 'None (1)'	System	17 Sep 2020 11:10:58

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:47', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a022bb05-fb1b-4c11-9d52-58fe52ccfb09' User entered 'No (N)'	System	17 Sep 2020 11:10:58
	System	17 Sep 2020 11:10:58



US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:50', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a022bb05-fb1b-4c11-9d52-58fe52ccfb09' User entered 'No (N)'	System	17 Sep 2020 11:10:58
	System	17 Sep 2020 11:10:58

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:53', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a022bb05-fb1b-4c11-9d52-58fe52ccfb09'	System	17 Sep 2020 11:10:58
User entered 'None (1)'	System	17 Sep 2020 11:10:58

**US3152194**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:56', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a022bb05-fb1b-4c11-9d52-58fe52ccfb09' User entered '17 Sep 2020 07:10'	System	17 Sep 2020 11:10:58
	System	17 Sep 2020 11:10:58

**US3152194**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 7'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:19:57', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fd8b6aef-6d64-45a7-ab02-4b24937d5965' User entered 'None (1)'	System	17 Sep 2020 23:20:09
	System	17 Sep 2020 23:20:09

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:19:59', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fd8b6aef-6d64-45a7-ab02-4b24937d5965' User entered 'No (N)'	System	17 Sep 2020 23:20:09
	System	17 Sep 2020 23:20:09



US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:01', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fd8b6aef-6d64-45a7-ab02-4b24937d5965' User entered 'No (N)'	System	17 Sep 2020 23:20:09
	System	17 Sep 2020 23:20:09

US3152194

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:04', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fd8b6aef-6d64-45a7-ab02-4b24937d5965' User entered 'None (1)'	System	17 Sep 2020 23:20:09
	System	17 Sep 2020 23:20:09

**US3152194**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:06', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'fd8b6aef-6d64-45a7-ab02-4b24937d5965'	System	17 Sep 2020 23:20:09
User entered '17 Sep 2020 19:20'	System	17 Sep 2020 23:20:09

**US3152194**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:17', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5f72ab4e-90ba-44c8-a014-6af82f98679e' User entered 'None (0)'	System	11 Sep 2020 19:03:51
	System	11 Sep 2020 19:03:51

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:19', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5f72ab4e-90ba-44c8-a014-6af82f98679e' User entered 'None (0)'	System	11 Sep 2020 19:03:51
	System	11 Sep 2020 19:03:51



**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:22', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5f72ab4e-90ba-44c8-a014-6af82f98679e' User entered 'None (0)'	System	11 Sep 2020 19:03:51
	System	11 Sep 2020 19:03:51

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:24', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5f72ab4e-90ba-44c8-a014-6af82f98679e' User entered 'None (0)'	System	11 Sep 2020 19:03:51
	System	11 Sep 2020 19:03:51

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:28', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5f72ab4e-90ba-44c8-a014-6af82f98679e' User entered 'None (0)'	System	11 Sep 2020 19:03:51
	System	11 Sep 2020 19:03:51

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:30', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5f72ab4e-90ba-44c8-a014-6af82f98679e' User entered 'None (0)'	System	11 Sep 2020 19:03:51
	System	11 Sep 2020 19:03:51

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:34', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5f72ab4e-90ba-44c8-a014-6af82f98679e' User entered 'No (N)'	System	11 Sep 2020 19:03:51
	System	11 Sep 2020 19:03:51

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T15:03:36', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '5f72ab4e-90ba-44c8-a014-6af82f98679e' User entered '11 Sep 2020 15:03'	System	11 Sep 2020 19:03:51
	System	11 Sep 2020 19:03:51

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '11 Sep 2020 14:51'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '11 Sep 2020 17:21'	System	11 Sep 2020 18:35:37



**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:47:59', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '2da1aa90-072c-42ae-bf89-ab02312c8312' User entered 'None (0)'	System	12 Sep 2020 02:48:23
	System	12 Sep 2020 02:48:23

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:48:02', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '2da1aa90-072c-42ae-bf89-ab02312c8312' User entered 'None (0)'	System	12 Sep 2020 02:48:23
	System	12 Sep 2020 02:48:23

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:48:04', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '2da1aa90-072c-42ae-bf89-ab02312c8312' User entered 'None (0)'	System	12 Sep 2020 02:48:23
	System	12 Sep 2020 02:48:23

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:48:09', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '2da1aa90-072c-42ae-bf89-ab02312c8312' User entered 'None (0)'	System	12 Sep 2020 02:48:23
	System	12 Sep 2020 02:48:23

**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:48:11', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '2da1aa90-072c-42ae-bf89-ab02312c8312' User entered 'None (0)'	System	12 Sep 2020 02:48:23
	System	12 Sep 2020 02:48:23

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:48:13', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '2da1aa90-072c-42ae-bf89-ab02312c8312' User entered 'None (0)'	System	12 Sep 2020 02:48:23
	System	12 Sep 2020 02:48:23

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:48:16', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '2da1aa90-072c-42ae-bf89-ab02312c8312' User entered 'No (N)'	System	12 Sep 2020 02:48:23
	System	12 Sep 2020 02:48:23



**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-11T22:48:19', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '2da1aa90-072c-42ae-bf89-ab02312c8312' User entered '11 Sep 2020 22:48'	System	12 Sep 2020 02:48:23
	System	12 Sep 2020 02:48:23

**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '11 Sep 2020 18:16'	System	11 Sep 2020 18:35:37

**US3152194**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 2'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:20', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '318dc5bf-4330-41c5-b4f0-8d93318e6f3c' User entered 'None (0)'	System	13 Sep 2020 01:44:38
	System	13 Sep 2020 01:44:38

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:22', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '318dc5bf-4330-41c5-b4f0-8d93318e6f3c' User entered 'None (0)'	System	13 Sep 2020 01:44:38
	System	13 Sep 2020 01:44:38

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:24', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '318dc5bf-4330-41c5-b4f0-8d93318e6f3c' User entered 'None (0)'	System	13 Sep 2020 01:44:38
	System	13 Sep 2020 01:44:38

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:26', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '318dc5bf-4330-41c5-b4f0-8d93318e6f3c' User entered 'None (0)'	System	13 Sep 2020 01:44:38
	System	13 Sep 2020 01:44:38



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:27', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '318dc5bf-4330-41c5-b4f0-8d93318e6f3c' User entered 'None (0)'	System	13 Sep 2020 01:44:38
	System	13 Sep 2020 01:44:38

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:29', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '318dc5bf-4330-41c5-b4f0-8d93318e6f3c' User entered 'None (0)'	System	13 Sep 2020 01:44:38
	System	13 Sep 2020 01:44:38

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:32', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '318dc5bf-4330-41c5-b4f0-8d93318e6f3c' User entered 'No (N)'	System	13 Sep 2020 01:44:38
	System	13 Sep 2020 01:44:38

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-12T21:44:34', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '318dc5bf-4330-41c5-b4f0-8d93318e6f3c' User entered '12 Sep 2020 21:44'	System	13 Sep 2020 01:44:38
	System	13 Sep 2020 01:44:38

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 3'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T19:59:57', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '24bf6e9d-9c2b-409f-a99e-9591d23aaf08' User entered 'None (0)'	System	14 Sep 2020 00:00:15
	System	14 Sep 2020 00:00:15



US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T20:00:00', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '24bf6e9d-9c2b-409f-a99e-9591d23aaf08' User entered 'None (0)'	System	14 Sep 2020 00:00:15
	System	14 Sep 2020 00:00:15

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T20:00:02', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '24bf6e9d-9c2b-409f-a99e-9591d23aaf08' User entered 'None (0)'	System	14 Sep 2020 00:00:15
	System	14 Sep 2020 00:00:15

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T20:00:04', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '24bf6e9d-9c2b-409f-a99e-9591d23aaf08' User entered 'None (0)'	System	14 Sep 2020 00:00:15
	System	14 Sep 2020 00:00:15

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T20:00:06', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '24bf6e9d-9c2b-409f-a99e-9591d23aaf08' User entered 'None (0)'	System	14 Sep 2020 00:00:15
	System	14 Sep 2020 00:00:15

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T20:00:08', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '24bf6e9d-9c2b-409f-a99e-9591d23aaf08' User entered 'None (0)'	System	14 Sep 2020 00:00:15
	System	14 Sep 2020 00:00:15

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T20:00:11', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '24bf6e9d-9c2b-409f-a99e-9591d23aaf08'	System	14 Sep 2020 00:00:15
User entered 'No (N)'	System	14 Sep 2020 00:00:15

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-13T20:00:13', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '24bf6e9d-9c2b-409f-a99e-9591d23aaf08'	System	14 Sep 2020 00:00:15
User entered '13 Sep 2020 20:00'	System	14 Sep 2020 00:00:15

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:35:37



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 4'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:26', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'e35b2c72-3ad7-4f19-b6ac-28fb136f7b30' User entered 'None (0)'	System	15 Sep 2020 10:15:48
	System	15 Sep 2020 10:15:48

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:29', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'e35b2c72-3ad7-4f19-b6ac-28fb136f7b30' User entered 'None (0)'	System	15 Sep 2020 10:15:48
	System	15 Sep 2020 10:15:48

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:30', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'e35b2c72-3ad7-4f19-b6ac-28fb136f7b30' User entered 'None (0)'	System	15 Sep 2020 10:15:48
	System	15 Sep 2020 10:15:48

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:32', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'e35b2c72-3ad7-4f19-b6ac-28fb136f7b30' User entered 'None (0)'	System	15 Sep 2020 10:15:48
	System	15 Sep 2020 10:15:48

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:34', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'e35b2c72-3ad7-4f19-b6ac-28fb136f7b30' User entered 'None (0)'	System	15 Sep 2020 10:15:48
	System	15 Sep 2020 10:15:48

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:37', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'e35b2c72-3ad7-4f19-b6ac-28fb136f7b30' User entered 'None (0)'	System	15 Sep 2020 10:15:48
	System	15 Sep 2020 10:15:48



US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:41', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'e35b2c72-3ad7-4f19-b6ac-28fb136f7b30' User entered 'No (N)'	System	15 Sep 2020 10:15:48
	System	15 Sep 2020 10:15:48

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T06:15:43', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'e35b2c72-3ad7-4f19-b6ac-28fb136f7b30' User entered '15 Sep 2020 06:15'	System	15 Sep 2020 10:15:48
	System	15 Sep 2020 10:15:48

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 5'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:15', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f3beb6f6-df53-45dd-a069-54abe94ce130' User entered 'None (0)'	System	15 Sep 2020 16:02:44
	System	15 Sep 2020 16:02:44

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:17', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f3beb6f6-df53-45dd-a069-54abe94ce130' User entered 'None (0)'	System	15 Sep 2020 16:02:44
	System	15 Sep 2020 16:02:44

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:18', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f3beb6f6-df53-45dd-a069-54abe94ce130' User entered 'None (0)'	System	15 Sep 2020 16:02:44
	System	15 Sep 2020 16:02:44



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:20', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f3beb6f6-df53-45dd-a069-54abe94ce130' User entered 'None (0)'	System	15 Sep 2020 16:02:44
	System	15 Sep 2020 16:02:44

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:22', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f3beb6f6-df53-45dd-a069-54abe94ce130' User entered 'None (0)'	System	15 Sep 2020 16:02:44
	System	15 Sep 2020 16:02:44

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:24', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f3beb6f6-df53-45dd-a069-54abe94ce130' User entered 'None (0)'	System	15 Sep 2020 16:02:44
	System	15 Sep 2020 16:02:44

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:26', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f3beb6f6-df53-45dd-a069-54abe94ce130' User entered 'No (N)'	System	15 Sep 2020 16:02:44
	System	15 Sep 2020 16:02:44

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-15T12:01:28', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f3beb6f6-df53-45dd-a069-54abe94ce130' User entered '15 Sep 2020 12:01'	System	15 Sep 2020 16:02:44
	System	15 Sep 2020 16:02:44

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 6'	System	11 Sep 2020 18:35:37



US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:10:59', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '91cb063f-3f97-472c-9a8f-681c8c593357' User entered 'None (0)'	System	17 Sep 2020 11:11:18
	System	17 Sep 2020 11:11:18

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:11:01', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '91cb063f-3f97-472c-9a8f-681c8c593357' User entered 'None (0)'	System	17 Sep 2020 11:11:18
	System	17 Sep 2020 11:11:18

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:11:03', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '91cb063f-3f97-472c-9a8f-681c8c593357' User entered 'None (0)'	System	17 Sep 2020 11:11:18
	System	17 Sep 2020 11:11:18

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:11:05', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '91cb063f-3f97-472c-9a8f-681c8c593357' User entered 'None (0)'	System	17 Sep 2020 11:11:18
	System	17 Sep 2020 11:11:18

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:11:08', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '91cb063f-3f97-472c-9a8f-681c8c593357' User entered 'None (0)'	System	17 Sep 2020 11:11:18
	System	17 Sep 2020 11:11:18

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:11:10', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '91cb063f-3f97-472c-9a8f-681c8c593357' User entered 'None (0)'	System	17 Sep 2020 11:11:18
	System	17 Sep 2020 11:11:18

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:11:13', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '91cb063f-3f97-472c-9a8f-681c8c593357' User entered 'No (N)'	System	17 Sep 2020 11:11:18
	System	17 Sep 2020 11:11:18

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T07:11:16', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '91cb063f-3f97-472c-9a8f-681c8c593357' User entered '17 Sep 2020 07:11'	System	17 Sep 2020 11:11:18
	System	17 Sep 2020 11:11:18



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	11 Sep 2020 18:35:37
User entered 'Day 7'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:09', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f20ff488-b316-456b-bded-8372e121652f' User entered 'None (0)'	System	17 Sep 2020 23:20:25
	System	17 Sep 2020 23:20:25

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:11', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f20ff488-b316-456b-bded-8372e121652f' User entered 'None (0)'	System	17 Sep 2020 23:20:25
	System	17 Sep 2020 23:20:25

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:12', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f20ff488-b316-456b-bded-8372e121652f' User entered 'None (0)'	System	17 Sep 2020 23:20:25
	System	17 Sep 2020 23:20:25

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:14', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f20ff488-b316-456b-bded-8372e121652f' User entered 'None (0)'	System	17 Sep 2020 23:20:25
	System	17 Sep 2020 23:20:25

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:16', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f20ff488-b316-456b-bded-8372e121652f' User entered 'None (0)'	System	17 Sep 2020 23:20:25
	System	17 Sep 2020 23:20:25



**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:17', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f20ff488-b316-456b-bded-8372e121652f' User entered 'None (0)'	System	17 Sep 2020 23:20:25
	System	17 Sep 2020 23:20:25

US3152194

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:20', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f20ff488-b316-456b-bded-8372e121652f' User entered 'No (N)'	System	17 Sep 2020 23:20:25
	System	17 Sep 2020 23:20:25

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-09-17T19:20:22', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'f20ff488-b316-456b-bded-8372e121652f' User entered '17 Sep 2020 19:20'	System	17 Sep 2020 23:20:25
	System	17 Sep 2020 23:20:25

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:35:37

**US3152194**

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

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

**Generated On: 09 Jun 2021 15:29:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:35:37

**US3152194**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:06:40

**US3152194**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered '18 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:06:40

**US3152194**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered 'Contact Made (CONTACT MADE)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:06:40



**US3152194**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered empty.	Priscilla Buahin (b) (4)	27 Oct 2020 17:06:40

**US3152194**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:06:46

**US3152194**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'I'	System	27 Oct 2020 17:06:46

**US3152194**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:07

**US3152194**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered '25 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:07

**US3152194**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered 'Contact Made (CONTACT MADE)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:07

**US3152194**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered empty.	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:07

**US3152194**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:35:56
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:17



**US3152194**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'I'	System	27 Oct 2020 17:07:17

**US3152194**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:44:21
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:29

**US3152194**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:44:21
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:29

**US3152194**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:44:21
User entered 'Contact Made (CONTACT MADE)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:29

**US3152194**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:44:21
User entered empty.	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:29

**US3152194**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 03:44:21
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:07:33

**US3152194**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'I'	System	27 Oct 2020 17:07:33

**US3152194**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:11:17



**US3152194**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '9 Oct 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:11:17

**US3152194**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Clinic (Clinic)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:11:17

**US3152194**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'VISIT3'	System	27 Oct 2020 17:11:17

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '9 Oct 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '08:21'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered '9 Oct 2020 08:21'	System	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '36.9' C	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14



**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Oral (Oral)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered empty.	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '60'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'bpm'	System	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '16'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'breaths/min'	System	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '139'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'mmHg'	System	27 Oct 2020 17:14:14



**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '88'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'mmHg'	System	27 Oct 2020 17:14:14

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13

**US3152194**

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

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:29:43**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13

**US3152194**

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

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:29:43**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:30

US3152194

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Oct 2020 17:14:42
User entered '9 Oct 2020' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:42
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	27 Oct 2020 17:14:30
User entered '9 Sep 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:14:30

**US3152194**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:15:00

US3152194

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '9 Oct 2020'	Priscilla Buahin (b) (4)	27 Oct 2020 17:15:00



**US3152194**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered '08:50'	Priscilla Buahin (b) (4)	27 Oct 2020 17:15:00

**US3152194**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered '9 Oct 2020 08:50'	System	27 Oct 2020 17:15:00

**US3152194**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	17 Feb 2021 04:36:11
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	27 Oct 2020 17:15:05

**US3152194**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'I'	System	27 Oct 2020 17:15:05

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 64'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-14T06:31:24', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4392656e-9ec2-4183-861b-01fa83114306'	System	14 Oct 2020 10:31:38
User entered 'No (N)'	System	14 Oct 2020 10:31:38

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-14T06:31:27', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4392656e-9ec2-4183-861b-01fa83114306'	System	14 Oct 2020 10:31:38
User entered 'No (N)'	System	14 Oct 2020 10:31:38

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-14T06:31:33', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4392656e-9ec2-4183-861b-01fa83114306' User entered '14 Oct 2020 06:31:33'	System	14 Oct 2020 10:31:38
	System	14 Oct 2020 10:31:38



**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 71'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-21T06:34:07', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a92d1921-459b-48af-bd68-da0b84dc2916' User entered 'Yes (Y)'	System	21 Oct 2020 10:35:08
	System	21 Oct 2020 10:35:08

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-21T06:34:14', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a92d1921-459b-48af-bd68-da0b84dc2916' User entered 'No (N)'	System	21 Oct 2020 10:35:08
	System	21 Oct 2020 10:35:08

US3152194

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:43

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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-21T06:34:23', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a92d1921-459b-48af-bd68-da0b84dc2916' User entered 'No (N)'	System	21 Oct 2020 10:35:08
	System	21 Oct 2020 10:35:08

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-21T06:34:29', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a92d1921-459b-48af-bd68-da0b84dc2916' User entered 'Yes (Y)'	System	21 Oct 2020 10:35:08
	System	21 Oct 2020 10:35:08

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Please 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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-21T06:34:48', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a92d1921-459b-48af-bd68-da0b84dc2916'	System	21 Oct 2020 10:35:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Oct 2020 10:35:08



**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-21T06:34:57', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a92d1921-459b-48af-bd68-da0b84dc2916' User entered '21 Oct 2020 06:34:57'	System	21 Oct 2020 10:35:08
	System	21 Oct 2020 10:35:08

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 78'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-28T07:19:54', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '1360652a-379e-45c9-9d16-3ddcd120340e' User entered 'Yes (Y)'	System	28 Oct 2020 11:20:27
	System	28 Oct 2020 11:20:27

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-28T07:19:58', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '1360652a-379e-45c9-9d16-3ddcd120340e' User entered 'No (N)'	System	28 Oct 2020 11:20:27
	System	28 Oct 2020 11:20:27

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-28T07:20:01', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '1360652a-379e-45c9-9d16-3ddcd120340e' User entered 'No (N)'	System	28 Oct 2020 11:20:27
	System	28 Oct 2020 11:20:27

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-28T07:20:08', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '1360652a-379e-45c9-9d16-3ddcd120340e' User entered 'Yes (Y)'	System	28 Oct 2020 11:20:27
	System	28 Oct 2020 11:20:27



**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Please 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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-28T07:20:13', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '1360652a-379e-45c9-9d16-3ddcd120340e'	System	28 Oct 2020 11:20:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Oct 2020 11:20:27

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-10-28T07:20:17', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '1360652a-379e-45c9-9d16-3ddcd120340e' User entered '28 Oct 2020 07:20:17'	System	28 Oct 2020 11:20:27
	System	28 Oct 2020 11:20:27

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 92'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-11T07:23:07', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '8e35400e-f03b-437d-9fd3-28b64c053f9c' User entered 'No (N)'	System	11 Nov 2020 12:23:19
	System	11 Nov 2020 12:23:19

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-11T07:23:10', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '8e35400e-f03b-437d-9fd3-28b64c053f9c' User entered 'No (N)'	System	11 Nov 2020 12:23:19
	System	11 Nov 2020 12:23:19

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-11T07:23:16', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '8e35400e-f03b-437d-9fd3-28b64c053f9c' User entered '11 Nov 2020 07:23:16'	System	11 Nov 2020 12:23:19
	System	11 Nov 2020 12:23:19



**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered 'Day 99'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-18T07:14:13', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '49b0c2bb-a69a-405e-af3b-74a69bcdeec'	System	18 Nov 2020 12:14:25
User entered 'No (N)'	System	18 Nov 2020 12:14:25

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-18T07:14:16', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '49b0c2bb-a69a-405e-af3b-74a69bcdeec'	System	18 Nov 2020 12:14:25
User entered 'No (N)'	System	18 Nov 2020 12:14:25

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-18T07:14:19', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '49b0c2bb-a69a-405e-af3b-74a69bcdeec' User entered '18 Nov 2020 07:14:19'	System	18 Nov 2020 12:14:25
	System	18 Nov 2020 12:14:25

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 14:35:56

**US3152194**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:41:11
Data entry locked.	System	14 Aug 2020 14:35:56
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 14:35:56



**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-25T06:44:34', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '9d79f8a5-bc3e-4c11-8484-633303282e55'	System	25 Nov 2020 11:44:51
User entered 'No (N)'	System	25 Nov 2020 11:44:51

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-25T06:44:41', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '9d79f8a5-bc3e-4c11-8484-633303282e55'	System	25 Nov 2020 11:44:51
User entered 'No (N)'	System	25 Nov 2020 11:44:51

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-25T06:44:46', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '9d79f8a5-bc3e-4c11-8484-633303282e55' User entered '25 Nov 2020 06:44:46'	System	25 Nov 2020 11:44:51
	System	25 Nov 2020 11:44:51

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-30T06:38:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '9c449d0f-98f6-4b6a-9007-a3c53758479b' User entered 'No (N)'	System	30 Nov 2020 11:38:45
	System	30 Nov 2020 11:38:45



**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-30T06:38:40', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '9c449d0f-98f6-4b6a-9007-a3c53758479b' User entered 'No (N)'	System	30 Nov 2020 11:38:45
	System	30 Nov 2020 11:38:45

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-11-30T06:38:43', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '9c449d0f-98f6-4b6a-9007-a3c53758479b' User entered '30 Nov 2020 06:38:43'	System	30 Nov 2020 11:38:45
	System	30 Nov 2020 11:38:45

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-07T09:39:21', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '471de3c0-b133-4225-9ea7-a36ae9c8118b' User entered 'No (N)'	System	07 Dec 2020 14:39:32
	System	07 Dec 2020 14:39:32

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-07T09:39:26', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '471de3c0-b133-4225-9ea7-a36ae9c8118b' User entered 'No (N)'	System	07 Dec 2020 14:39:32
	System	07 Dec 2020 14:39:32

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-07T09:39:30', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '471de3c0-b133-4225-9ea7-a36ae9c8118b' User entered '07 Dec 2020 09:39:30'	System	07 Dec 2020 14:39:32
	System	07 Dec 2020 14:39:32



**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-15T09:53:59', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4c27023d-48a0-476c-983b-deb949782557'	System	15 Dec 2020 14:54:10
User entered 'No (N)'	System	15 Dec 2020 14:54:10

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-15T09:54:02', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4c27023d-48a0-476c-983b-deb949782557'	System	15 Dec 2020 14:54:10
User entered 'No (N)'	System	15 Dec 2020 14:54:10

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-15T09:54:05', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '4c27023d-48a0-476c-983b-deb949782557'	System	15 Dec 2020 14:54:10
User entered '15 Dec 2020 09:54:05'	System	15 Dec 2020 14:54:10

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:03:02



**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-22T12:05:27', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c72565f8-c59a-43fa-98ed-7f7602a75863'	System	22 Dec 2020 17:06:05
User entered 'Yes (Y)'	System	22 Dec 2020 17:06:05

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-22T12:05:04', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c72565f8-c59a-43fa-98ed-7f7602a75863'	System	22 Dec 2020 17:06:05
User entered 'No (N)'	System	22 Dec 2020 17:06:05

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-22T12:05:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c72565f8-c59a-43fa-98ed-7f7602a75863'	System	22 Dec 2020 17:06:05
User entered 'No (N)'	System	22 Dec 2020 17:06:05

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-22T12:05:44', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c72565f8-c59a-43fa-98ed-7f7602a75863'	System	22 Dec 2020 17:06:05
User entered 'No (N)'	System	22 Dec 2020 17:06:05

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-22T12:06:03', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'c72565f8-c59a-43fa-98ed-7f7602a75863' User entered '22 Dec 2020 12:06:03'	System	22 Dec 2020 17:06:05
	System	22 Dec 2020 17:06:05

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:03:02



**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-28T17:17:53', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'bc794746-986f-4fda-9dda-8fa55dbbf947'	System	28 Dec 2020 22:18:08
User entered 'No (N)'	System	28 Dec 2020 22:18:08

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-28T17:18:00', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'bc794746-986f-4fda-9dda-8fa55dbbf947'	System	28 Dec 2020 22:18:08
User entered 'No (N)'	System	28 Dec 2020 22:18:08

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2020-12-28T17:18:06', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'bc794746-986f-4fda-9dda-8fa55dbbf947' User entered '28 Dec 2020 17:18:06'	System	28 Dec 2020 22:18:08
	System	28 Dec 2020 22:18:08

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2021-01-07T12:13:47', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a0a0c3eb-d1bd-4e63-95a0-625958ee286c' User entered 'No (N)'	System	07 Jan 2021 17:14:06
	System	07 Jan 2021 17:14:06



**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Have you been exposed to someone with 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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2021-01-07T12:13:59', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a0a0c3eb-d1bd-4e63-95a0-625958ee286c'	System	07 Jan 2021 17:14:06
User entered 'No (N)'	System	07 Jan 2021 17:14:06

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2021-01-07T12:14:02', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: 'a0a0c3eb-d1bd-4e63-95a0-625958ee286c' User entered '07 Jan 2021 12:14:02'	System	07 Jan 2021 17:14:06
	System	07 Jan 2021 17:14:06

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2021-01-10T00:01:32', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '940fe45d-34d8-452d-b74c-44300933f5b8'	System	10 Jan 2021 05:01:52
User entered 'No (N)'	System	10 Jan 2021 05:01:52

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

Have you been exposed to someone with 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)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2021-01-10T00:01:35', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '940fe45d-34d8-452d-b74c-44300933f5b8'	System	10 Jan 2021 05:01:52
User entered 'No (N)'	System	10 Jan 2021 05:01:52

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3544E3DB-50ED-4109-8EE1-757CC1080279)', Time: '2021-01-10T00:01:38', User OID: 'PatientReportedOutcome (US3152194)', ODM File OID: '940fe45d-34d8-452d-b74c-44300933f5b8' User entered '10 Jan 2021 00:01:38'	System	10 Jan 2021 05:01:52
	System	10 Jan 2021 05:01:52



**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:29:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:03:02
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:03:02

**US3152194**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	18 Nov 2020 16:03:22

**US3152194**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '3 Nov 2020'	Priscilla Buahin (b) (4)	18 Nov 2020 16:03:22

**US3152194**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'Contact Made (CONTACT MADE)'	Priscilla Buahin (b) (4)	18 Nov 2020 16:03:22

**US3152194**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered empty.	Priscilla Buahin (b) (4)	18 Nov 2020 16:03:22

**US3152194**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	18 Nov 2020 16:03:28

**US3152194**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:39:13
User entered 'I'	System	18 Nov 2020 16:03:28



**US3152194**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:28
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	11 Dec 2020 20:17:42

**US3152194**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:28
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '11 Dec 2020'	Jemario Blackwell (b) (4)	11 Dec 2020 20:17:42

**US3152194**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:28
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'Contact Made (CONTACT MADE)'	Jemario Blackwell (b) (4)	11 Dec 2020 20:17:42

**US3152194**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:28
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered empty.	Jemario Blackwell (b) (4)	11 Dec 2020 20:17:42

**US3152194**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:28
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'Yes (Y)'	Jemario Blackwell (b) (4)	11 Dec 2020 20:17:49

**US3152194**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:13:28
User entered 'I'	System	11 Dec 2020 20:17:49

**US3152194**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:36:23
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Feb 2021 18:15:35

US3152194

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:36:23
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 14:09:04
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Subject was not reachable after multiple attempts, and end of study page completed as a result of information provided once reached ' (Site from System).		27 Feb 2021 18:16:43
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	27 Feb 2021 18:15:35
User entered '15 Jan 2021'	(b) (4), (b) (6)	27 Feb 2021 18:15:35



**US3152194**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:36:23
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Feb 2021 18:15:35

**US3152194**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:29:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:36:23
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	(b) (4), (b) (6)	27 Feb 2021 18:15:35

**US3152194**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:36:23
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'No (N)'	(b) (4), (b) (6)	27 Feb 2021 18:16:49

**US3152194**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:36:23
User entered empty.	System	27 Feb 2021 18:16:49

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'No (N)'	Juliana DeVito (b) (4)	30 Mar 2021 13:05:25

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered empty.	Juliana DeVito (b) (4)	30 Mar 2021 13:05:25

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered empty.	Juliana DeVito (b) (4)	30 Mar 2021 13:05:25

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:29:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered 'UNBLND_DECIDE'	System	30 Mar 2021 13:05:25



**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered empty.	Juliana DeVito (b) (4)	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'I'	Juliana DeVito (b) (4)	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'Amendment 5 (Amendment 5)'	Juliana DeVito (b) (4)	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered '05 Nov 2020'	Juliana DeVito (b) (4)	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'Placebo (Placebo)'	Juliana DeVito (b) (4)	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'Placebo (Placebo)'	Juliana DeVito (b) (4)	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'Placebo (Placebo)'	Juliana DeVito (b) (4)	30 Mar 2021 13:06:56
	(b) (4)	



**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'No (N)'	Juliana DeVito (b) (4)	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:29:43**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered empty.	System	30 Mar 2021 13:06:56

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'No (N)'	Juliana DeVito (b) (4)	30 Mar 2021 13:09:25

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered empty.	Juliana DeVito (b) (4)	30 Mar 2021 13:09:25

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered empty.	Juliana DeVito (b) (4)	30 Mar 2021 13:09:25

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:29:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered empty.	System	30 Mar 2021 13:09:25

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:29:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'No (N)'	Juliana DeVito (b) (4)	30 Mar 2021 13:09:31



**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:29:43**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered empty.	Juliana DeVito (b) (4)	30 Mar 2021 13:09:31

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:29:43**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered empty.	Juliana DeVito (b) (4)	30 Mar 2021 13:09:31

**US3152194**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:29:43**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered empty.	System	30 Mar 2021 13:09:31

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:29:43**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:36
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	02 Oct 2020 20:31:09

US3152194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
Reviewed for Safety.		05 Oct 2020 12:47:53
User entered 'USA-US073-2020-mRNA-1273-P301000002'	System	05 Oct 2020 12:47:48
User entered 'New'	(b) (4), (b) (6)	05 Oct 2020 12:47:48

US3152194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'PV Query: Please consider reporting 2 serious adverse event terms "BILATERAL PULMONARY EMBOLISM" and "PULMONARY INFARCTS", by updated SAE to BILATERAL PULMONARY EMBOLISM, and creating a separate SAE of PULMONARY INFARCTS.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:42:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 19:10:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Dec 2020 19:10:31
Data point term sent to Coder	System	18 Dec 2020 19:08:29
Query 'PV Query: Please consider reporting 2 serious adverse event terms "BILATERAL PULMONARY EMBOLISM" and "PULMONARY INFARCTS", by updated SAE to BILATERAL PULMONARY EMBOLISM, and creating a separate SAE of PULMONARY INFARCTS.' answered with 'completed per sponsors request' (Site from Safety).	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:08:16
Coding entries removed.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:08:11
User entered 'BILATERAL PULMONARY EMBOLISM' reason for change: Per Query Resolution	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:08:11
User opened query 'PV Query: Please consider reporting 2 serious adverse event terms "BILATERAL PULMONARY EMBOLISM" and "PULMONARY INFARCTS", by updated SAE to BILATERAL PULMONARY EMBOLISM, and creating a separate SAE of PULMONARY INFARCTS.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:38:56

US3152194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:27:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:27:40
Data point term sent to Coder	System	23 Nov 2020 20:44:43
Query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' canceled (Site from System).	Coder Import (b) (4)	23 Nov 2020 20:43:57
User opened query 'For coding purposes, please split to report each event separately, in different entries (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	18 Nov 2020 17:14:48
Data point term sent to Coder	System	18 Nov 2020 16:05:35
DataPoint Un-verified.	Priscilla Buahin (b) (4)	18 Nov 2020 16:05:11
Coding entries removed.	Priscilla Buahin (b) (4)	18 Nov 2020 16:05:11
User entered 'bilateral PULMONARY EMBOLISM with pulmonary infarcts' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	18 Nov 2020 16:05:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:17:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 21:17:54
Data point term sent to Coder	System	02 Oct 2020 21:16:48
User entered 'Pulmonary Embolism'	(b) (4), (b) (6)	02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'Yes (Y)'		02 Oct 2020 21:16:14



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'No (N)'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'No (N)'		02 Oct 2020 21:16:14

US3152194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:25:57
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (21 Sep 2020). If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 17:03:23
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (21 Sep 2020). If not, please clarify.' answered with 'Data edited to when symptoms started ' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 17:23:25
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 17:22:54
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:27
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (21 Sep 2020). If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 15:21:15
User entered '02 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 21:16:14

US3152194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 22:16:53
User entered empty; reason for change Data Entry Error		02 Oct 2020 22:16:53
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		02 Oct 2020 21:16:14
User entered '14:22'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered empty.	System	02 Oct 2020 22:16:53
User entered '02 Oct 2020 14:22'	System	02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Nov 2020 15:20:35
DataPoint Un-verified.	Juliana DeVito (b) (4)	25 Nov 2020 15:20:35
User entered 'No (N)' reason for change: Data Entry Error	Juliana DeVito (b) (4)	25 Nov 2020 15:20:35
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Nov 2020 15:20:21
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'Yes (Y)'		02 Oct 2020 21:16:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 16:10:32
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' answered with 'updated' (Site from Safety).	Juliana DeVito (b) (4) (b) (4)	25 Nov 2020 15:32:47
DataPoint Un-verified.	Juliana DeVito (b) (4) (b) (4)	25 Nov 2020 15:20:21
User entered '16 Oct 2020' reason for change: Data Entry Error	Juliana DeVito (b) (4) (b) (4)	25 Nov 2020 15:20:21
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:45:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		16 Nov 2020 20:06:53

US3152194

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Patient does not have end date as of yet and still being followed by hematologist for condition.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:41:08
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		06 Nov 2020 16:30:52
DataPoint Verified.		30 Oct 2020 17:25:57
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		28 Oct 2020 17:03:27
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'AE ongoing' (Site from Safety).		27 Oct 2020 17:25:40
DataPoint Un-verified.		27 Oct 2020 13:45:25
DataPoint Verified.		27 Oct 2020 13:45:05
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		12 Oct 2020 15:20:49
User entered empty.		02 Oct 2020 21:16:14



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered empty.	System	02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'Grade 3/Severe (Grade 3/Severe)'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'Yes (Y)'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.		02 Oct 2020 21:16:14



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'l'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'Not Related (NOT RELATED)'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'Not Related (NOT RELATED)'		02 Oct 2020 21:16:14



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:25:57
User closed query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		28 Oct 2020 17:03:33
Query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'data updated per query' (Site from Safety).		27 Oct 2020 17:24:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		27 Oct 2020 17:24:26
DataPoint Un-verified.		27 Oct 2020 13:45:21
DataPoint Verified.		27 Oct 2020 13:45:05
User opened query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		12 Oct 2020 15:21:54
User entered 'None (NONE)'		02 Oct 2020 21:16:14

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'		02 Oct 2020 21:16:14

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'l'		02 Oct 2020 21:16:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	09 Apr 2021 02:32:19
User closed query 'Per DM CLR RQ: Response noted. However, please review and update the "other action taken" accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:05:22
Query 'Per DM CLR RQ: Response noted. However, please review and update the "other action taken" accordingly.' answered with 'con procedure removed as other action taken' (Site from DM).	Juliana DeVito (b) (4)	22 Mar 2021 17:44:23
Signature has been broken.	(b) (4)	22 Mar 2021 17:44:12
User entered '0' reason for change: Data Entry Error	Juliana DeVito (b) (4)	22 Mar 2021 17:44:12
User opened query 'Per DM CLR RQ: Response noted. However, please review and update the "other action taken" accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 09:01:31
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 09:01:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'an action taken was to get those diagnostic procedures done. we will update it to not indicate con procedure per this query' (Site from DM).	Juliana DeVito (b) (4)	04 Mar 2021 20:58:15
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 03:19:11
DataPoint Un-verified.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:18:43

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EAB) (1725)

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Oyebisi Olanrewaju	18 Dec 2020 19:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'		02 Oct 2020 21:16:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 16:42:40
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'see narrative regarding outcome ' (Site from Safety).	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:08:43
DataPoint Un-verified.	Juliana DeVito (b) (4)	25 Nov 2020 15:20:21
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Juliana DeVito (b) (4)	25 Nov 2020 15:20:21
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 15:46:01
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 20:07:04
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Event has not yet been resolved. Patient is still under care and expected to be under care for a while until the condition is stable and deemed under control.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:43:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 16:31:12
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		05 Nov 2020 23:37:06
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AE not expected to resolve. ' (Site from Safety).	Azure Erskine (b) (4) (b) (4)	04 Nov 2020 18:18:23
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:25:57
DataPoint Un-verified.		27 Oct 2020 13:45:19
DataPoint Verified.		27 Oct 2020 13:45:05
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		12 Oct 2020 15:21:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'		02 Oct 2020 21:16:14

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**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Un-verified.	Juliana DeVito (b) (4)	25 Nov 2020 15:20:21
User entered 'Condition is stable and ongoing but patient must take xarelto for PE prophylaxis.' reason for change: New Information	Juliana DeVito (b) (4)	25 Nov 2020 15:20:21
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.		02 Oct 2020 21:16:14



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User closed query 'SQ Query: Please consider removing either Hashimoto's thyroiditis or chronic lymphocytic thyroiditis from medical history as they are names for the same condition.' (Site from Safety).		09 Apr 2021 15:45:16
Query 'SQ Query: Please consider removing either Hashimoto's thyroiditis or chronic lymphocytic thyroiditis from medical history as they are names for the same condition.' answered with 'done' (Site from Safety).	Juliana DeVito (b) (4) (b) (4)	08 Apr 2021 13:17:16
User opened query 'SQ Query: Please consider removing either Hashimoto's thyroiditis or chronic lymphocytic thyroiditis from medical history as they are names for the same condition.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:49:56
User closed query 'Per DM CLR: SAE Narrative = PT WAS EVALUATED BY HEMATOLOGY ON 02 OCT, 2020 AND STARTED ON LOVENOX INJECTIONS TWICE DAILY FOR 14 DAYS. PLANS TO START XARELTO TREATMENT UPON COMPLETION OF LOVENOX. Please review if ConMed #5 already ended and should be updated with an end date and XARELTO should be recorded. Review and update eCRF as appropriate.' (Site from DM).		10 Mar 2021 07:03:06
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
Query 'Per DM CLR: SAE Narrative = PT WAS EVALUATED BY HEMATOLOGY ON 02 OCT, 2020 AND STARTED ON LOVENOX INJECTIONS TWICE DAILY FOR 14 DAYS. PLANS TO START XARELTO TREATMENT UPON COMPLETION OF LOVENOX. Please review if ConMed #5 already ended and should be updated with an end date and XARELTO should be recorded. Review and update eCRF as appropriate.' answered with 'will review conmeds and update as appropriate.' (Site from DM).	Juliana DeVito (b) (4) (b) (4)	04 Mar 2021 20:59:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:43

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = PT WAS EVALUATED BY HEMATOLOGY ON 02 OCT, 2020 AND STARTED ON LOVENOX INJECTIONS TWICE DAILY FOR 14 DAYS. PLANS TO START XARELTO TREATMENT UPON COMPLETION OF LOVENOX. Please review if ConMed #5 already ended and should be updated with an end date and XARELTO should be recorded. Review and update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 03:19:04
		30 Oct 2020 17:25:57
User closed query 'PV Query: Please provide if the subject had presence of DVT or usual risk factors for PE such as estrogen treatment, immobility, long distance travel, severe obesity, other underlying diseases, etc.' (Site from Safety).		28 Oct 2020 17:03:59
User closed query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		28 Oct 2020 17:03:56
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results' (Site from Safety).		28 Oct 2020 17:03:46
Query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Due to the large amount of lab and diagnostic data available, please clarify how the information should be submitted.' (Site from Safety).		27 Oct 2020 20:26:22
Query 'PV Query: Please provide if the subject had presence of DVT or usual risk factors for PE such as estrogen treatment, immobility, long distance travel, severe obesity, other underlying diseases, etc.' answered with 'History of hypertension, on Carvedilol.		27 Oct 2020 17:33:01
Travelled to North Carolina by car in end of September.' (Site from Safety).		
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results' answered with 'No' (Site from Safety).		27 Oct 2020 17:26:08

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:15
DataPoint Verified.		27 Oct 2020 13:45:05
User opened query 'PV Query: Please provide if the subject had presence of DVT or usual risk factors for PE such as estrogen treatment, immobility, long distance travel, severe obesity, other underlying diseases, etc.' (Site from Safety).		12 Oct 2020 15:21:44
User opened query 'PV Query: Please provide any additional relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		12 Oct 2020 15:21:00
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results' (Site from Safety).		12 Oct 2020 15:20:33
User entered 'Pt reported that she had one episode of right sided chest pain on 21 Sep, 2020, which lasted for a few hours then resolved spontaneously. She did not seek medical attention back then but was treated with Medrol dose pack (Pt is an MD). Reports her orthopedic colleague ordered a CT scan for her back pain (hxo L4-L5 discectomy) which incidentally revealed acute and subacute pulmonary embolism on 02 OCT, 2020. Pt was evaluated by hematology on 02 OCT, 2020 and started on Lovenox injections twice daily for 14 days. Plans to start Xarelto treatment upon completion of Lovenox. States she is asymptomatic at this time. Medical records pending.'		02 Oct 2020 21:16:14

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**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	02 Oct 2020 21:16:14

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered 'I'	System	02 Oct 2020 21:16:14

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:43**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	Ipsita Abalokita (b) (4)	02 Nov 2020 20:37:16
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:25:57
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 23:08:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 23:08:32
Data point term sent to Coder	System	27 Oct 2020 20:22:48
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'Right chest pain was unspecified at time of data collection of AE. ' (Site from DM). Coding entries removed.	(b) (4), (b) (6)	27 Oct 2020 20:22:22
User entered 'Unspecified right chest pain' reason for change: Data Entry Error		27 Oct 2020 20:22:15
DataPoint Un-verified.		27 Oct 2020 13:45:42
DataPoint Verified.		27 Oct 2020 13:45:05



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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:11:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Chest wall pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:06:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:06:21
Data point term sent to Coder	System	09 Oct 2020 14:55:44
User entered 'right chest wall pain'	Tanya Alexander (b) (4) (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4) (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4) (b) (4)	07 Oct 2020 19:46:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '21 Sep 2020'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User entered empty.	System	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:43**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '21 Sep 2020'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User entered empty.	System	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	(b) (4) Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

US3152194

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

US3152194

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'Not Related (NOT RELATED)'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered 'Not Related (NOT RELATED)'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 14:56:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 14:56:12
User entered 'None (NONE)' reason for change: Data Entry Error	Tanya Alexander (b) (4)	09 Oct 2020 14:56:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	09 Oct 2020 14:55:44
	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	(b) (4)	
	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03
	(b) (4)	

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Un-verified.	Jemario Blackwell (b) (4)	06 Feb 2021 21:58:53
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Jemario Blackwell (b) (4)	06 Feb 2021 21:58:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '1'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Un-verified.	Jemario Blackwell (b) (4)	06 Feb 2021 21:58:53
User entered '1' reason for change: Data Entry Error	Jemario Blackwell (b) (4)	06 Feb 2021 21:58:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered '0'	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 14:56:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Oct 2020 14:56:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Tanya Alexander (b) (4)	09 Oct 2020 14:56:12
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Oct 2020 14:55:44
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
	(b) (4)	
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03
	(b) (4)	

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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 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:29:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:45:05
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User entered '0'	System	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
User entered '0'	System	09 Oct 2020 14:55:44
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03
	(b) (4)	

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:45
DataPoint activated with code reason code Data required.	Tanya Alexander (b) (4)	09 Oct 2020 14:54:38
DataPoint inactivated with code reason code Data not required.	Priscilla Buahin (b) (4)	07 Oct 2020 19:46:03

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:29:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 18:33:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 18:33:27
Data point term sent to Coder	System	04 Nov 2020 18:32:01
User entered 'pleural effusion'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'No (N)'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'No (N)'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'No (N)'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '22 Sep 2020'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User entered empty.	System	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'No (N)'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '02 Oct 2020'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User entered empty.	System	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Grade 1/Mild (Grade 1/Mild)'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'No (N)'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Azure Erskine (b) (4)	04 Nov 2020 18:31:05



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Not Related (NOT RELATED)'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Not Related (NOT RELATED)'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'None (NONE)'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'I'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 18:31:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 18:31:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:31:14
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 18:31:05
User entered empty.	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[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 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Azure Erskine (b) (4)	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User entered '0'	System	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49
User entered '0'	System	04 Nov 2020 18:31:05

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:09:49

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 16:44:23
User entered 'USA-US073-2020-mRNA-1273-P301000002'		21 Dec 2020 16:44:18



US3152194

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary infarction, LLT: Pulmonary infarct - version MedDRA\\23.0.	Coder Import (b) (4)	19 Dec 2020 20:23:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Dec 2020 20:23:44
Data point term sent to Coder	System	18 Dec 2020 19:12:33
User entered 'bilateral pulmonary infarcts'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'No (N)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '02 Oct 2020'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered empty.	System	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 19:15:55
User entered 'No (N)' reason for change: Data Entry Error	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:15:55
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	18 Dec 2020 19:14:24
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15



US3152194

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Dec 2020 19:14:24
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	18 Dec 2020 19:14:24
User entered '16 Oct 2020' reason for change: Per Query Resolution	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:14:24
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Dec 2020 19:12:15
User entered empty.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered empty.	System	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Grade 3/Severe (Grade 3/Severe)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Yes (Y)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'I'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Not Related (NOT RELATED)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

US3152194

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:43

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable ' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:26:13
Query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable ' answered with 'Action taken with IP has been updated ' (Site from Safety).		24 Dec 2020 17:56:21
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution		24 Dec 2020 17:55:51
User opened query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable ' (Site from Safety).		23 Dec 2020 16:22:28
User entered 'None (NONE)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'I'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

US3152194

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).		10 Mar 2021 09:03:07
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0' reason for change: Data Entry Error	Juliana DeVito (b) (4)	04 Mar 2021 21:00:28
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' answered with 'will update per query but diagnostic procedures are recorded on conprocedure log indicated for this AE because that was the action taken once diagnosis was made. updating per DM request ' (Site from DM).	Juliana DeVito (b) (4)	04 Mar 2021 21:00:04
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 03:19:34
User entered '1'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Xarelto for prophylaxis'	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Dec 2020 19:15:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Dec 2020 19:15:55
User entered 'AE term divided per sponsors request initial AE termed Bilateral Pulmonary Embolism with bilateral infarcts' reason for change: Per Query Resolution	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:15:55
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Dec 2020 19:12:15
User entered empty.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:12:15



**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered 'I'	System	18 Dec 2020 19:12:15

**US3152194**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:29:43

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User closed query 'Per ETRTR: Please add details of Medication dosed for SAE "Pulmonary Embolism", thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 00:06:00
DataPoint Verified.		28 Oct 2020 14:52:10
Query 'Per ETRTR: Please add details of Medication dosed for SAE "Pulmonary Embolism", thanks.' answered with 'updated' (Site from CRA).	Tanya Alexander (b) (4)	09 Oct 2020 14:53:54
User opened query 'Per ETRTR: Please add details of Medication dosed for SAE "Pulmonary Embolism", thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 22:53:06
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:44:45

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 13:21:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Aug 2020 13:21:37
Data point term sent to Coder	System	21 Aug 2020 14:46:14
User entered 'carvedilol ER'	Azure Erskine (b) (4) (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'hypertension'	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '40'	Azure Erskine (b) (4)	21 Aug 2020 14:45:29



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'mg (mg)'	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'once daily (QD)'	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'Oral (ORAL)'	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	21 Aug 2020 14:47:17
User entered 'un UNK 2019' reason for change: Data Entry Error	Azure Erskine (b) (4)	21 Aug 2020 14:47:17
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 14:45:29
User entered empty.	System	21 Aug 2020 14:45:29
	Azure Erskine (b) (4)	21 Aug 2020 14:45:29
	(b) (4)	

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:45:29



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	21 Aug 2020 14:45:29

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '804 (804)'	System	21 Aug 2020 14:45:29

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B 12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 11:01:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 11:01:40
Data point term sent to Coder	System	21 Aug 2020 14:47:17
User entered 'Vitamin B-12'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20
	(b) (4)	

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'nutritional supplement'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '25'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).		29 Sep 2020 16:28:17
Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'Updated to appropriate dose unit' (Site from DM).	Azure Erskine (b) (4)	16 Sep 2020 13:17:50
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	16 Sep 2020 13:17:31
User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 01:08:47
User entered 'Other (OTHER)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty; reason for change Data Entry Error	Azure Erskine (b) (4)	16 Sep 2020 13:17:31
User entered 'mcg'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'once daily (QD)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'Oral (ORAL)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:46:20



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'un UNK 2019'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	21 Aug 2020 14:46:20

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '804 (804)'	System	21 Aug 2020 14:46:20



US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: BIFIDOBACTERIUM INFANTIS, PRODUCTSYNONYM: ALIGN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:48:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:48:24
Data point term sent to Coder	System	21 Aug 2020 14:47:19
User entered 'Align Probiotic'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'nutritional supplement'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'I'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'capsule (CAPSULE)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'once daily (QD)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:46:58



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'Oral (ORAL)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'un Feb 2020'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '0'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'Yes (Y)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Azure Erskine (b) (4)	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	21 Aug 2020 14:46:58



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	21 Aug 2020 14:46:58

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '804 (804)'	System	21 Aug 2020 14:46:58

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:30:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:30:32
User closed query 'Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 17:44:18
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Query 'Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' answered with 'updated' (Site from DM).	Jemario Blackwell (b) (4) (b) (4)	06 Feb 2021 21:57:24
User opened query 'Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 12:35:21
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL [METHYLPREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 10:44:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 10:44:33
Data point term sent to Coder	System	29 Oct 2020 15:02:18

PRODUCTION RELEASE (v12.003  
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US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:43

Name of Medication

Audit	User	Time (GMT)
Coding entries removed.	Priscilla Buahin (b) (4)	29 Oct 2020 15:01:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 13:41:00
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL [METHYLPREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 15:10:29
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 Oct 2020 15:10:29
Data point term sent to Coder	System	09 Oct 2020 14:52:38
User entered 'medrol dose pack'	Tanya Alexander (b) (4) (b) (4)	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User closed query 'Per DM CLR: Please note that the AE linked to this CM does not match this Con Med timeframe. Please review Con Med use and reconcile with AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Dec 2020 00:10:01
Query 'Per DM CLR: Please note that the AE linked to this CM does not match this Con Med timeframe. Please review Con Med use and reconcile with AE eCRF as appropriate.' answered with 'corrected' (Site from DM).	Azure Erskine (b) (4)	23 Dec 2020 15:56:06
User opened query 'Per DM CLR: Please note that the AE linked to this CM does not match this Con Med timeframe. Please review Con Med use and reconcile with AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
DataPoint Un-verified.	Priscilla Buahin (b) (4)	29 Oct 2020 15:01:45
User entered 'Unspecified right chest pain' reason for change: Data Entry Error	(b) (4)	
	Priscilla Buahin (b) (4)	29 Oct 2020 15:01:45
DataPoint Verified.	(b) (4)	
	(b) (4)	27 Oct 2020 13:41:00
User entered 'bilateral pulmonary emboli'	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08
	(b) (4)	

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '4'	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'mg (mg)'	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'other (OTHER)'	Tanya Alexander (b) (4) (b) (4)	09 Oct 2020 14:52:08

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'dose pack	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08
6 tabs	(b) (4)	
5 tabs		
4 tabs		
3 tabs		
2 tabs		
1 tab'		

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'Oral (ORAL)'	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE (21SEP2020). Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Dec 2020 00:10:08
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE (21SEP2020). Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'updated' (Site from DM).	Azure Erskine (b) (4)	23 Dec 2020 15:55:56
DataPoint Un-verified.	Azure Erskine (b) (4)	23 Dec 2020 15:55:46
User entered '21 Sep 2020' reason for change: Data Entry Error	Azure Erskine (b) (4)	23 Dec 2020 15:55:46
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE (21SEP2020). Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:08:54
DataPoint Verified.	(b) (4)	27 Oct 2020 13:41:00
User entered '22 Sep 2020'	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '0'	Tanya Alexander (b) (4) (b) (4)	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '27 Sep 2020'	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User entered empty.	System	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User entered empty.	System	09 Oct 2020 14:52:08

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:42
User entered empty.	System	09 Oct 2020 14:52:08

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:03:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 16:03:38
Data point term sent to Coder	System	23 Dec 2020 15:55:14
Coding entries removed.	Azure Erskine (b) (4) (b) (4)	23 Dec 2020 15:54:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:17:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:17:17
Data point term sent to Coder	System	29 Oct 2020 15:02:18
Coding entries removed.	Priscilla Buahin (b) (4) (b) (4)	29 Oct 2020 15:02:05
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LOVENOX [LEVOFLOXACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 21:11:34

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:43

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Oct 2020 21:11:34
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	09 Oct 2020 14:53:41
User entered 'lovenox'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19
	(b) (4)	

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19



US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:28:18
DataPoint Un-verified.	Priscilla Buahin (b) (4)	29 Oct 2020 15:02:05
User entered 'BILATERAL PULMONARY EMBOLI with pulmonary infarcts' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	29 Oct 2020 15:02:05
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'bilateral pulmonary emboli'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '70'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'mg (mg)'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'twice daily (BID)'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Dec 2020 00:10:22
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Updated' (Site from DM).	Azure Erskine (b) (4)	23 Dec 2020 15:54:52
DataPoint Un-verified.	Azure Erskine (b) (4)	23 Dec 2020 15:54:43
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Azure Erskine (b) (4)	23 Dec 2020 15:54:43
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:06:32
DataPoint Verified.		27 Oct 2020 13:41:00
User entered 'Oral (ORAL)'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '02 Oct 2020'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered '0'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User signature succeeded.	(b) (4)	23 Feb 2021 17:44:45
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Un-verified.	Jemario Blackwell (b) (4)	06 Feb 2021 21:58:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Feb 2021 21:58:17
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:52:25
DataPoint Verified.	(b) (4)	27 Oct 2020 13:41:00
User entered 'Yes (Y)'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Un-verified.	Jemario Blackwell (b) (4)	06 Feb 2021 21:58:17
User entered '16 Oct 2020' reason for change: Data Entry Error	Jemario Blackwell (b) (4)	06 Feb 2021 21:58:17
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered empty.	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 13:41:00
User entered 'No (N)'	Tanya Alexander (b) (4)	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User entered '2'	System	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User entered '1'	System	09 Oct 2020 14:53:19

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:29:46
User entered '804 (804)'	System	09 Oct 2020 14:53:19



US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:18:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:18:46
Data point term sent to Coder	System	29 Oct 2020 14:44:46
User entered 'calcium'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Dec 2020 00:10:35
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	Azure Erskine (b) (4)	23 Dec 2020 15:56:32
DataPoint Un-verified.	(b) (4)	23 Dec 2020 15:56:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Azure Erskine (b) (4)	23 Dec 2020 15:56:24
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 06:06:11
DataPoint Verified.	(b) (4)	18 Nov 2020 16:47:46
User entered 'No (N)'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered 'nutritional supplement'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered '600'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered 'mg (mg)'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered empty.	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered 'once daily (QD)'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered empty.	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered 'Oral (ORAL)'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered empty.	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered 'un Apr 2020'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered '0'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered empty.	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:47:46
User entered 'No (N)'	Priscilla Buahin (b) (4)	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	29 Oct 2020 14:44:17



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	29 Oct 2020 14:44:17

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '804 (804)'	System	29 Oct 2020 14:44:17

US3152194

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 21:02:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 21:02:40
Data point term sent to Coder	System	04 Mar 2021 21:02:36
User entered 'xarelto'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23
	(b) (4)	

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'pulmonary embolism prophylaxis'	Juliana DeVito (b) (4) (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '20'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'mg (mg)'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'once daily (QD)'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Oral (ORAL)'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23
	(b) (4)	

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '16 Oct 2020'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '0'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'Yes (Y)'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered empty.	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23



**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'No (N)'	Juliana DeVito (b) (4)	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '1'	System	04 Mar 2021 21:02:23

**US3152194**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '804 (804)'	System	04 Mar 2021 21:02:23

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:29:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:35:38
User entered 'Yes (Y)'	Priscilla Buahin (b) (4)	02 Nov 2020 15:53:35

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '8 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:02:09

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'echocardiogram'	Priscilla Buahin (b) (4)	02 Nov 2020 16:02:09

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:02:09



**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:02:09

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:24:48
User closed query '2 Oct per source' (Site from CRA).		22 Feb 2021 11:57:27
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Query '2 Oct per source' answered with 'reconciled with source ' (Site from CRA).	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:19:29
DataPoint Un-verified.	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:19:25
User entered '2 Oct 2020' reason for change: Per Query Resolution	Oyebisi Olanrewaju (b) (4)	18 Dec 2020 19:19:25
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User opened query '2 Oct per source' (Site from CRA).		18 Nov 2020 16:41:53
User entered '2 Nov 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:03:10

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:24:48
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'factor v leiden'	Priscilla Buahin (b) (4)	02 Nov 2020 16:03:10

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:29:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:24:48
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:03:10

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:24:48
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:03:10

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:24:59
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:04:39

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:24:59
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'protein c'	Priscilla Buahin (b) (4)	02 Nov 2020 16:04:39

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:24:59
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:04:39



US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:24:59
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:04:39

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 15:29:43**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:02
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:05:14

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:02
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'lupus anticoagulant panel'	Priscilla Buahin (b) (4)	02 Nov 2020 16:05:14

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:02
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:05:14

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:29:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:02
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:05:14

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:10
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:05:40

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:10
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'protein s'	Priscilla Buahin (b) (4)	02 Nov 2020 16:05:40

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:29:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:10
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:05:40



**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:10
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:05:40

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:12
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:06:17

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:12
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'antithrombin III antigen panel'	Priscilla Buahin (b) (4)	02 Nov 2020 16:06:17

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:12
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:06:17

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:12
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:06:17

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 15:29:43**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:14
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:06:51

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:14
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'cardiolipin antibody panel'	Priscilla Buahin (b) (4)	02 Nov 2020 16:06:51

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:14
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:06:51



**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:14
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:06:51

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 09 Jun 2021 15:29:43**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:17
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:08:39

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:17
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'beta 2 glycoprotein 1'	Priscilla Buahin (b) (4)	02 Nov 2020 16:08:39

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:29:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:17
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:08:39

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:29:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:17
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:08:39

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:19
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:09:29

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:19
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'homocysteine panel'	Priscilla Buahin (b) (4)	02 Nov 2020 16:09:29

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:19
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:09:29



**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (9)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:19
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:09:29

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:22
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:10:07

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:22
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'comprehensive metabolic panel'	Priscilla Buahin (b) (4)	02 Nov 2020 16:10:07

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:29:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:22
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:10:07

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 15:29:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:25:22
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:10:07

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:49
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:10:37

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:49
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'CBC with auto differentials'	Priscilla Buahin (b) (4)	02 Nov 2020 16:10:37

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 15:29:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:49
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:10:37



**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (11)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:49
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:10:37

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '7 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:11:24

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'venous doppler ultrasound dvt protocol bilateral legs'	Priscilla Buahin (b) (4)	02 Nov 2020 16:11:24

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (12)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:11:24

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 15:29:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:52
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:11:24

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:55
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '6 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:12:09

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 15:29:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:55
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'computed tomography abdomen and pelvis with contrast'	Priscilla Buahin (b) (4)	02 Nov 2020 16:12:09

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (13)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:55
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:12:09



**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (13)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:39:55
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:12:09

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:40:00
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:38:51
User entered '2 Oct 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:12:45

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (14)**

**Generated On: 09 Jun 2021 15:29:43**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:40:00
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:38:55
User entered 'computed tomography chest with contrast'	Priscilla Buahin (b) (4)	02 Nov 2020 16:12:45

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (14)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:40:00
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:38:57
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:12:45

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (14)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:40:00
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:38:59
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:12:45

US3152194

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 09 Jun 2021 15:29:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:40:06
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered '22 Sep 2020'	Priscilla Buahin (b) (4)	02 Nov 2020 16:13:28

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (15)**

**Generated On: 09 Jun 2021 15:29:43**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:40:06
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'magnetic resonance imaging thoracic spine without contrast'	Priscilla Buahin (b) (4)	02 Nov 2020 16:13:28

**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (15)**

**Generated On: 09 Jun 2021 15:29:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:40:06
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered 'Adverse Event (AE)'	Priscilla Buahin (b) (4)	02 Nov 2020 16:13:28



**US3152194**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (15)**

**Generated On: 09 Jun 2021 15:29:43**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:40:06
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:46:22
User entered empty.	Priscilla Buahin (b) (4)	02 Nov 2020 16:13:28

**US3152194**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 09 Jun 2021 15:29:43**

**Date of study discontinuation/completion** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:31:50
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '15 Jan 2021'	(b) (4), (b) (6)	18 Jan 2021 16:29:49

US3152194

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:29:43

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:31:50
User signature succeeded.	Shishir Khetan (b) (4)	17 Mar 2021 01:50:22
Signature has been broken.	Priscilla Buahin (b) (4)	16 Mar 2021 17:38:41
User entered 'Protocol deviation (specify (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Priscilla Buahin (b) (4)	16 Mar 2021 17:38:41
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'Other (OTHER)'	(b) (4), (b) (6)	18 Jan 2021 16:29:49

**US3152194**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 09 Jun 2021 15:29:43**

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:31:50
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'Subject received an EUA outside of study on 16Dec2020.'	(b) (4), (b) (6)	18 Jan 2021 16:29:49

**US3152194**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 09 Jun 2021 15:29:43**

[If reason for discontinuation is Death, main cause of death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:31:50
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 16:29:49

**US3152194**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 09 Jun 2021 15:29:43**

[If main cause of death is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:31:50
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 16:29:49

**US3152194**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 09 Jun 2021 15:29:43**

**Date of death** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:31:50
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 16:29:49

**US3152194**

**Folder: End of Study (1)**

**Form: End of Study / Study Discontinuation**

**Generated On: 09 Jun 2021 15:29:43**

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:31:50
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered empty.	(b) (4), (b) (6)	18 Jan 2021 16:29:49



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'		05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48



US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'		05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
	(b) (4)	

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Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48



US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
	(b) (4)	

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:29:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User entered '05/Oct/2020 08:48'	System	05 Oct 2020 12:48:15

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:29:43

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'I'		05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:29:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 17:25:21
User entered '28/Oct/2020 13:05'	System	28 Oct 2020 17:05:25

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:29:43

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
DataPoint Verified.		30 Oct 2020 17:25:21
User entered 'I'		28 Oct 2020 17:05:25

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48



US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:29:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '19/Nov/2020 14:11'	System	19 Nov 2020 19:11:58

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:29:43

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
User entered 'I'		19 Nov 2020 19:11:58

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48



US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:29:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '30/Nov/2020 11:10'	System	30 Nov 2020 16:11:01

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:29:43

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 16:44:50
User entered 'I'		30 Nov 2020 16:11:01



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48



US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:29:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '21/Dec/2020 11:45'	System	21 Dec 2020 16:45:02

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:29:43

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 20:26:27
User entered 'I'		21 Dec 2020 16:45:02

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 15:29:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '28/Dec/2020 20:26'	System	28 Dec 2020 20:26:40

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:29:43

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Reviewed for Safety.		05 Mar 2021 14:52:36
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered 'I'	(b) (4), (b) (6)	28 Dec 2020 20:26:40

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 15:29:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered '05/Mar/2021 09:52'	System	05 Mar 2021 14:52:57

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:29:43

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
Reviewed for Safety.		23 Mar 2021 16:21:55
User signature succeeded.	Shishir Khetan (b) (4)	08 Mar 2021 13:16:03
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 14:52:57

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48



US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (8)**

**Generated On: 09 Jun 2021 15:29:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered '23/Mar/2021 11:22'	System	23 Mar 2021 16:22:09

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:29:43

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 16:22:09



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'USA-US073-2020-MRNA-1273-P301000002'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

**Serious**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'No (N)'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Yes (Y)'	System	05 Oct 2020 12:47:48



US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Brandon'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Shishir' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Brandon'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Essink'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User closed query 'Wrong PI entered. Correction needed' (Site from CRA).		11 Nov 2020 02:10:36
Query 'Wrong PI entered. Correction needed' answered with 'Correct PI entered accordingly ' (Site from CRA).	Azure Erskine (b) (4)	04 Nov 2020 18:23:30
Un-reviewed for Safety.	(b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Khetan' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
User opened query 'Wrong PI entered. Correction needed' (Site from CRA).		27 Oct 2020 13:29:51
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Essink'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '3319 N 107th'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '1201 Seven Locks Road' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '3319 N 107th'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered 'Omaha'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered 'Rockville' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered 'Omaha'	System	05 Oct 2020 12:47:48

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered empty.	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
User entered 'MD'	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
	(b) (4)	

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:43

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:10:48
Un-reviewed for Safety.	System	19 Nov 2020 19:11:58
User entered '68134'	System	19 Nov 2020 19:11:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 19:11:44
Un-reviewed for Safety.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Un-verified.	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
User entered '20852' reason for change: Data Entry Error	Azure Erskine (b) (4)	04 Nov 2020 18:23:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:00:54
Reviewed for Safety.		05 Oct 2020 12:48:10
User entered '68134'	System	05 Oct 2020 12:47:48

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 17:04:14
DataPoint Verified.		27 Oct 2020 14:00:54
User entered 'US'	System	05 Oct 2020 12:48:15

**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:29:43**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User entered '9'	System	09 Apr 2021 15:46:28
User entered '8'	System	23 Mar 2021 16:22:09
User entered '7'	System	05 Mar 2021 14:52:57
User signature succeeded.	Shishir Khetan (b) (4)	19 Feb 2021 19:05:26
User entered '6'	System	28 Dec 2020 20:26:40
User entered '5'	System	21 Dec 2020 16:45:02
User entered '4'	System	30 Nov 2020 16:11:01
User entered '3'	System	19 Nov 2020 19:11:58
User entered '2'	System	28 Oct 2020 17:05:25
User entered '1'	System	05 Oct 2020 12:48:15



**US3152194**

**Folder: SAE USA-US073-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (9)**

**Generated On: 09 Jun 2021 15:29:43**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered '09/Apr/2021 08:46'	System	09 Apr 2021 15:46:28

US3152194

Folder: SAE USA-US073-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:29:43

**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)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:26:31
User signature succeeded.	Shishir Khetan (b) (4)	28 Apr 2021 17:21:04
User entered 'I'	(b) (4), (b) (6)	09 Apr 2021 15:46:28