

US3432094 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:31:57

All time stamps listed in this document are displayed in GMT

US3432094

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 00:08:11

Generated On: 09 Jun 2021 17:31:57

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Participant ID

US3432094

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

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US3432094

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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

Visit date (dd MMM yyyy)	11 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	SCRN
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Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 16 Feb 2021 00:08:14

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 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) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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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) 16 Feb 2021 00:08:14

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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) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	HISTORY OF LEUKEMIA
Start date (dd MMM yyyy)	UN NOV 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN SEP 2007
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)	SEP 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	CORONARY STENT
Start date (dd MMM yyyy)	UN SEP 2007
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 SEP 2007
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2007
Start Year (derived)	2007
Stop Month and Year (derived)	SEP 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	LOW VITAMIN D
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	ESOPHAGEAL REFLUX
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 25 Apr 2021 11:00:29

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Condition	MENINGIOMA
Start date (dd MMM yyyy)	UN NOV 2011
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)	NOV 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

Condition	SURGICAL RESECTION FOR MENINGIOMA
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:10
Height ( <i>xxx.x</i> )	174 cm
Weight ( <i>xxx.x</i> )	90.6 kg
BMI ( <i>xxx.x</i> )	29.92469 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 00:08:14

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 00:08:14

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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**

RETIRED PHYSICIAN

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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) 16 Feb 2021 00:08:14

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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)	True
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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

Visit date (dd MMM yyyy)	11 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) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185402

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) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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)	11 AUG 2020
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:10
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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)	11 AUG 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:53
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)	46 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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 AUG 2020

What was the treatment time? (00:00-23:59) 15:22 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 15:22

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) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 11 AUG 2020

Collection time (00:00-23:59) 14:20 (24 HR)

Collection date and time (derived) 11 AUG 2020 14:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:25	11 AUG 2020 14:25
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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 17:31:57

**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

98.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 11 AUG 2020 16:00

PC Open Date & Time 11 AUG 2020 15:42

PC Close Date & Time 11 AUG 2020 18:12

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**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 96.3 °F

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

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

PC Time Stamp	11 AUG 2020 23:21
PC Open Date & Time	11 AUG 2020 19:07
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 23:13

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

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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

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 23:16

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

14 AUG 2020 18:31

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °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

15 AUG 2020 23:16

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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**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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 22:58

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**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

97.0 °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 AUG 2020 23:38

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**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

11 AUG 2020 16:01

PC Open Date & Time

11 AUG 2020 15:42

PC Close Date & Time

11 AUG 2020 18:12

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**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 AUG 2020 23:22

PC Open Date & Time

11 AUG 2020 19:07

PC Close Date & Time

12 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

50

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 23:14

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

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

20

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 23:17

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

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

15

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 18:32

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

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

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 23:17

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**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

16 AUG 2020 22:59

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**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 AUG 2020 23:38

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**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 ☐

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 16:01
PC Open Date & Time	11 AUG 2020 15:42
PC Close Date & Time	11 AUG 2020 18:12

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**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 ☐

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 23:23
PC Open Date & Time	11 AUG 2020 19:07
PC Close Date & Time	12 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 23:15
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



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Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 23:17
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 18:32
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 23:17
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**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 ☒



US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 23:39
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 8

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 ☐

PC Time Stamp 18 AUG 2020 23:19

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:31:57

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 AUG 2020 23:19
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3432094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3432094

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3432094

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3432094

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 00:08:15

Generated On: 09 Jun 2021 17:31:57

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

Visit date (dd MMM yyyy)	10 SEP 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	VISIT2
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US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 00:08:37

Generated On: 09 Jun 2021 17:31:57

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	9:06 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 9:06
Temperature (xxx.x)	98.1 F
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)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 00:08:37

Generated On: 09 Jun 2021 17:31:57

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:35
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3432094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 SEP 2020

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 10:05

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

What was the frequency of the study treatment dosing? ONCE

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

US3432094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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

Collection date (dd MMM yyyy)	10 SEP 2020
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Collection time (00:00-23:59)	9:50 (24 HR)
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Collection date and time (derived)	10 SEP 2020 9:50
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US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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



US3432094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**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

10 SEP 2020 10:42

PC Open Date & Time

10 SEP 2020 10:25

PC Close Date & Time

10 SEP 2020 12:55

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**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 97.6 °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	10 SEP 2020 21:44
PC Open Date & Time	10 SEP 2020 13:50
PC Close Date & Time	11 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	11 SEP 2020 18:37
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	12 SEP 2020 22:29
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 00:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 22:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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**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

97.5 °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 21:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**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

96.9 °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

17 SEP 2020 00:20

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 10:43

PC Open Date & Time

10 SEP 2020 10:25

PC Close Date & Time

10 SEP 2020 12:55

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

15

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 21:45

PC Open Date & Time

10 SEP 2020 13:50

PC Close Date & Time

11 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

30

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

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

40

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 22:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

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

Yes ☒

No ☐

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

50

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

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

Yes ☒

No ☐

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

50

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 00:00

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

50

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

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

Yes ☒

No ☐

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

40

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 22:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**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 ☐

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

40

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

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

Yes ☒

No ☐

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

40

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:55

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

15

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 00:21

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**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 ☐

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 10:43
PC Open Date & Time	10 SEP 2020 10:25
PC Close Date & Time	10 SEP 2020 12:55

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**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 ☐

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 21:46
PC Open Date & Time	10 SEP 2020 13:50
PC Close Date & Time	11 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**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 ☒

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:39
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 22:31
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**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

105 of 2991

EAB) (1725)

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 00:01
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**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 ☒

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 22:12
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:56
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**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 ☒



US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 00:21
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 8

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 ☐

PC Time Stamp 17 SEP 2020 20:09

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(9)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 9

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 ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(10)

Generated On: 09 Jun 2021 17:31:57

---

**TIMEPOINT**

DAY 10

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 ☐

---

PC Time Stamp

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PC Open Date & Time

19 SEP 2020 12:00

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PC Close Date & Time

20 SEP 2020 11:59

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US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT

DAY 8

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

Yes ☒

No ☐

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

10

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

PC Time stamp

17 SEP 2020 20:10

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(9)

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT

DAY 9

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

Yes ☐

No ☐

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

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

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(10)

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT

DAY 10

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

Yes ☐

No ☐

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

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

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 20:10

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59



US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:31:57

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 20:10
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:31:57

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

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:31:57

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3432094

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3432094

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3432094

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 00:08:37

Generated On: 09 Jun 2021 17:31:57

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 00:08:37

Generated On: 09 Jun 2021 17:31:57

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	09:54 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 09:54
Temperature (xxx.x)	037.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	047 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	067 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 00:08:37

Generated On: 09 Jun 2021 17:31:57

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

8 OCT 2020

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

---

US3432094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 00:08:37

Generated On: 09 Jun 2021 17:31:57

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

Collection date (dd MMM yyyy)	8 OCT 2020
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Collection time (00:00-23:59)	09:58 (24 HR)
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Collection date and time (derived)	8 OCT 2020 09:58
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US3432094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:37

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 OCT 2020 12:08:30
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 12:04:48

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59



US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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	29 OCT 2020 12:08:46
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**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 12:36:35

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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26 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2020 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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03 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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07 DEC 2020 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2020 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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14 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JAN 2021 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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04 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 FEB 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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11 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 222

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 MAR 2021 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 229

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 MAR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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29 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 MAY 2021 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUN 2021 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 SEP 2021 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2021 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 516

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

No ☐  
Yes ☐

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

No ☐  
Yes ☐

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

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

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

No ☐  
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 FEB 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 FEB 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 MAR 2022 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 APR 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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21 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

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**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2022 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 AUG 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2022 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2022 23:59



US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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

**US3432094**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

13 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 OCT 2022 23:59

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**US3432094**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 17:31:57**

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

US3432094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

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*

US3432094

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:14

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Was Contact Attempted? Yes ☐  
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

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

Comments

*If Contact Not Made, please provide Comments*

PT. IN ICU AT THE TIME OF  
CALL, BUT BEING MONITORED  
THROUGH EPIC. WILL  
ATTEMPT FOLLOW-UP IF PT'S  
CONDITION IMPROVES.



US3432094

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3432094

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3432094

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Was this visit performed? Yes ☐  
No ☒

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

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

Folder OID VISIT4

US3432094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

US3432094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

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.*



US3432094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3432094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3432094**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3432094**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3432094**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:31:57**

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"/>

**US3432094**

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

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

**Generated On: 09 Jun 2021 17:31:57**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3432094

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

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

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

US3432094

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Date of updated informed consent ( <i>dd MMM yyyy</i> )	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	6 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	



US3432094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3432094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3432094

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 00:08:11

Generated On: 09 Jun 2021 17:31:57

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:57

AEID	
Adverse event	INSECT BITE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	7 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)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:57

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	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)	_____

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:57

AEID

Adverse event

IPILATERAL  
LYMPHADENOPATHY (RIGHT  
POSTERIOR CERVICAL CHAIN,  
RIGHT POSTERIOR  
MANDIBULAR, RIGHT  
SUPRACLAVICULAR)

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) 10 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) 08 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 ☐

PRODUCTION RELEASE (v12.003

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:57

	No	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
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 type="checkbox"/>
	Related	<input checked="" type="checkbox"/>
	Not Applicable	<input type="checkbox"/>
Relationship to Study Procedure	Not Related	<input checked="" type="checkbox"/>
	Related	<input type="checkbox"/>
	Not Applicable	<input type="checkbox"/>
Action taken with investigational product	None	<input checked="" type="checkbox"/>
	Dose Delayed	<input type="checkbox"/>
	Investigational Product	<input type="checkbox"/>
	Withdrawn	<input type="checkbox"/>
	Not Applicable	<input type="checkbox"/>
<hr/>		
Other action taken (check all that apply)		
None	True	
Concomitant Medication	False	
Concomitant Procedure	False	
Outcome	Fatal	<input type="checkbox"/>
	Not Recovered/Not Resolved	<input type="checkbox"/>
	Recovered/Resolved	<input checked="" type="checkbox"/>
	Recovered/Resolved with Sequelae	<input type="checkbox"/>
	Recovering/Resolving	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
<hr/>		
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		
<hr/>		
Serious Adverse Event Derived (CSA Programming Field Only)	0	
Medically Attended AE Derived (CSA Programming Field Only)	0	
Admitted to ICU Derived (CSA Programming Field Only)		

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

AEID	USA-US078-2020-MRNA-1273-P30 1000015
Adverse event	PROGRESSION OF MENINGIOMA
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)	28 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	23 DEC 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	24
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

WE HAD REPORTED SURGERY  
AND HOSPITALIZATION FOR  
MENINGIOMA AS A SEPARATE  
SAE, WHICH WE SUBSUMED  
AND ARE COMBINING IN THIS  
AE.

AT ENROLLMENT,  
PARTICIPANT REPORTED THAT  
MENINGIOMA WAS RESOLVED  
IN 2012 (HAD A SURGICAL  
RESECTION). IN RETROSPECT,  
SERIAL MRI OVER THE LAST  
2-3 YEARS SHOWED SOME  
GROWTH TO HIS MENINGIOMA,  
FOR WHICH AN ELECTIVE  
SURGERY WAS PLANNED  
AFTER THE RESULT OF THE  
MRI DONE ON 10/28/2020  
(INTERVAL INCREASED  
NODULAR ENHANCEMENT  
ADJACENT TO THE LEFT  
PARIETAL CRANIOTOMY SITE  
INCLUDING A L  
PARASAGITTAL COMPONENT  
EXTENDING INTO THE  
SUPERIOR SAGITTAL SINUS).  
PARTICIPANT HAD A  
CRANIOPLASTY AND  
CRANIECTOMY FOR  
MENINGIOMA. WHILE IN THE  
HOSPITAL, PARTICIPANT THEN  
SUFFERED FROM AN  
INTRA-OPERATIVE  
MEDICATION INDUCED  
HYPERTENSIVE  
INTRAPARENCHYMAL  
HEMORRHAGE.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

US3432094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:57

AEID	
Adverse event	INJECTION SITE PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	10 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)	17 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:57

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3432094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:31:57

AEID	
Adverse event	SWELLING AT INJECTION SITE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	10 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)	17 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

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Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

AEID	USA-US078-2020-MRNA-1273-P30 1000015
Adverse event	ALTERED MENTAL STATUS
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)	27 DEC 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)	4 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	4 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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	



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

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PARTICIPANT WITH HISTORY  
OF MENINGIOMA S/P LEFT  
CRANIOTOMY FOR RESECTION  
AND CRANIOPLASTY  
(23NOV2020), PRESENTS TO ED  
FROM REHAB WITH ALTERED  
MENTAL STATUS ON  
29DEC2020 AND ADMITTED ON  
30DEC2020. REHABILITATION  
CENTER NOTES THAT  
PARTICIPANT HAS BECOME  
MORE FATIGUE AND  
LETHARGIC STARTING  
27DEC2020. CT SCAN ON  
29DEC2020 FOUND NO  
ABNORMALITIES.  
COVID TESTING- ALL NP  
SWABS, ALL NEGATIVE  
(DATES: 12/30/20, 12/31/20)

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

AEID	USA-US078-2021-MRNA-1273-P30 1000013
Adverse event	HEMATOCHEZIA
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)	30 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	2 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	05 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (8)

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

---

PT STARTED HAVING  
HEMOTOCHYZIA, BRBPR, IN  
THE SETTING OF RECENT LGIB  
DUE TO RECTAL TUBE  
TRAUMA AND RECTAL ULCER  
ON JAN 30TH 2021. 1-2X/ DAY  
SINCE. HAD 3 EPISODES ON  
2/1/21. PRESENTED TO ED ON  
2/2/21 AND ADMITTED LATER  
THAT DAY. HAD FLEXIBLE  
SIGMOIDOSCOPY 03FEB2021  
SHOWING THE RECTAL ULCER.  
COVID TESTING IN HOSPITAL-  
ALL NP SWABS, ALL NEGATIVE  
(DATES: 2/2/21. 2/3/21)

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:31:57

AEID	USA-US078-2020-MRNA-1273-P30 1000015
Adverse event	INTRA-OPERATIVE MEDICATION INDUCED HYPERTENSIVE INTRAPARENCHYMAL HEMORRHAGE
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)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	23 DEC 2020
Admitted to ICU?	Yes <input checked="" type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (9)

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	No	<input type="checkbox"/>
	Unknown	<input type="checkbox"/>
Number of Days in ICU		24
Persistent or significant disability or incapacity		False
Congenital anomaly or birth defect		False
Other medically important event		False
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
Other action taken (check all that apply)		
None		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 type="radio"/>
	Recovering/Resolving	<input checked="" type="radio"/>
	Unknown	<input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
<hr/>		
Narrative		

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:31:57

---

THIS EVENT OCCURRED  
UNDER THE SAE  
"PROGRESSION OF  
MENINGIOMA" WHILE THE  
PARTICIPANT WAS IN THE  
HOSPITAL FOR A PLANNED  
CRANIECTOMY. WE WERE  
INSTRUCTED TO ENTER THIS  
EVENT AS A SEPARATE AE.  
OCCURRED DURING LEFT  
CRANIECTOMY FOR  
RESECTION AND  
CRANIOPLASTY (SCHEDULED  
PROCEDURE PLANNED FOR  
PROGRESSION OF  
MENINGIOMA). EVENT  
PROLONGED  
HOSPITALIZATION.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication PRE-EXISTING  
HYPOTHYROIDISM

Dose per administration 150

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIOVASCULAR  
PROPHYLAXIS

Dose per administration 81

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	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)	UN UNK 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication IRBESARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 150

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	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 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	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 2003	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication BUPROPION

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	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 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication PRILOSEC

Prophylaxis Yes ☐  
No ☒

Indication ESOPHAGEAL REFLUX

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	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 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication SORENESS AT INJECTION SITE

Dose per administration 1000

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication DUCOLAX

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	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 checked="" 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)		23 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication COLACE

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 50/5

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify MG/ML

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	23 NOV 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication COLACE

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	23 NOV 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN AFTER CRANIOPLASTY  
AND CRANIECTOMY

Dose per administration 650

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

Q6 HOURS PRN

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	24 NOV 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)		
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 (13)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication ATROPINE

Prophylaxis Yes ☐  
No ☒

Indication BRADYCARDIA

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication OFIRMEV

Prophylaxis Yes ☐  
No ☒

Indication PAIN AFTER CRANIOPLASTY  
AND CRANIECTOMY

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

Q6 HOURS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication FLUID RETENTION TREATMENT

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication FLUID RETENTION TREATMENT

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication FLUID RETENTION TREATMENT

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication LEXAPRO

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY FROM SURGERY

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication DILAUDID

Prophylaxis Yes ☐  
No ☒

Indication SEVERE PAIN AFTER  
CRANIOPLASTY AND  
CRANIECTOMY

Dose per administration 0.5-1

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

Q4 HOURS PRN

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (20)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐  
No ☒

Indication HIGH BLOOD PRESSURE

Dose per administration 5-10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

Q4 HOURS PRN

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication INFLAMMATION (GENERAL)

Dose per administration TAPERED DOSAGE

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify 8 MG 04DEC20-05DEC20; 6 MG  
05DEC2020-09DEC2020; 4 MG  
09DEC2020-12DEC2020; 2 MG  
12DEC2020- ONGOING

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input checked="" type="checkbox"/>
If route of administration is Other, specify	NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	04 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication HEPARIN

Prophylaxis Yes ☐  
No ☒

Indication ANTICOAGULANT

Dose per administration 490.1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS/HOUR

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 CONTINUOUS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication ESOMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTRIC REFLUX

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication ANCEF

Prophylaxis Yes ☒  
No ☐

Indication BACTERIAL INFECTION  
PREVENTION

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

Q8H PRN

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication FLUID RETENTION TREATMENT

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication FLUID RETENTION TREATMENT

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Form: Prior/Concomitant Medication and Vaccination (27)

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Name of Medication DUONEB

Prophylaxis Yes ☐  
No ☒

Indication SHORTNESS OF BREATH

Dose per administration 3

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

Q4 HOUR PRN

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		NEBULIZATION
Start date (dd MMM yyyy)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (28)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication HEPARIN

Prophylaxis Yes ☐  
No ☒

Indication ANTICOAGULANT

Dose per administration 5000

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication DULCOLAX

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	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)		23 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
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 (30)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication PEPCID

Prophylaxis Yes ☐  
No ☒

Indication ANTIACID

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	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)		23 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication HYDROCORTISONE

Prophylaxis Yes ☐  
No ☒

Indication ADRENAL INSUFFICIENCY

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	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)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication HYDROCORTISONE

Prophylaxis Yes ☐  
No ☒

Indication ADRENAL INSUFFICIENCY

Dose per administration 15

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	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)		05 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 05 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication HYDROCORTISONE

Prophylaxis Yes ☐  
No ☒

Indication ADRENAL INSUFFICIENCY

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	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)	06 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 12 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication BACTEREMIA

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNK

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☒  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

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Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication BACTEREMIA

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐  
No ☒

Indication BACTEREMIA

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



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Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 04 Apr 2021 20:33:27

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Name of Medication POLYETHYLENE GLYCOL  
(MIRALAX)

Prophylaxis Yes ☐  
No ☒

Indication CONSTIPATION

Dose per administration 17

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Name of Medication HEPARIN

Prophylaxis Yes ☐  
No ☒

Indication COAGULANT PROPHYLAXIS

Dose per administration 5000

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNITS/ML

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

	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)		23 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 00:08:13

Generated On: 09 Jun 2021 17:31:57

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 04 Apr 2021 20:33:27

Generated On: 09 Jun 2021 17:31:57

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 NOV 2020	CRANIECTOMY	Medical History	
23 NOV 2020	CRANIOPLASTY	Medical History	
29 DEC 2020	CT SCAN HEAD	Adverse Event	
2 FEB 2021	CT ABDOMEN AND PELVIS	Adverse Event	
28 OCT 2020	MRI BRAIN	Adverse Event	
03 FEB 2021	FLEXIBLE SIGMOIDOSCOPY	Adverse Event	

US3432094

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:31:57

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3432094

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:31:57

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐



US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/NOV/2020 18:54
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

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/DEC/2020 15:41
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

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/JAN/2021 20:03
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

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/JAN/2021 15:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/FEB/2021 11:40
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

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/FEB/2021 09:00
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2020-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/APR/2021 10:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3432094

Folder: SAE USA-US078-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3432094

Folder: SAE USA-US078-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/FEB/2021 07:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432094

Folder: SAE USA-US078-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/APR/2021 11:42
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

US3432094

Folder: SAE USA-US078-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Apr 2021 11:00:29

Generated On: 09 Jun 2021 17:31:57

SAEID	USA-US078-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/APR/2021 10:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3432094 (Prod: Brigham and Womens Hospital)

**US3432094**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:31:57**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'US3432094'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:49:43

**US3432094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	11 Aug 2020 19:13:54

**US3432094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:49:44



**US3432094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[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 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	11 Aug 2020 19:13:54

**US3432094**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'SCRN'	System	11 Aug 2020 19:13:54

US3432094

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:57

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:49:45

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '76'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User entered 'YEARS'	System	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User entered '76'	System	11 Aug 2020 19:14:28

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Male (M)'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12



**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'I'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12



**US3432094**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:31:57**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:57

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Aug 2020'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:28

**US3432094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:57**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User entered 'Aug 2020'	System	11 Aug 2020 19:14:28

**US3432094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:57**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User entered '2020'	System	11 Aug 2020 19:14:28

**US3432094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:57**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Amendment 2 (2)'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:28

**US3432094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:57**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:28

**US3432094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:57**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Bruce Bausk (b) (4)	11 Aug 2020 19:14:28

**US3432094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:57**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Bruce Bausk (b) (4)	11 Aug 2020 19:14:28



**US3432094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:57**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:28

**US3432094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:57**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:49:44

**US3432094**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:31:57**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User entered 'I'	System	11 Aug 2020 19:14:33

**US3432094**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:31:57**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:33

**US3432094**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 17:31:57**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	11 Aug 2020 19:14:38

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Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Leukaemias, HLT: Leukaemias NEC, PT: Leukaemia, LLT: Leukemia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 12:53:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 12:53:24
Data point term sent to Coder	System	11 Aug 2020 20:27:14
User entered 'History of leukemia'	Bruce Bausk (b) (4)	11 Aug 2020 20:26:21

**US3432094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'un Nov 2011'	Bruce Bausk (b) (4)	11 Aug 2020 20:26:21

**US3432094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 20:26:21



**US3432094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Bruce Bausk (b) (4)	11 Aug 2020 20:26:21

**US3432094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'un UNK 2012'	Bruce Bausk (b) (4)	11 Aug 2020 20:26:21

**US3432094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 20:26:21

**US3432094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Nov 2011'	System	11 Aug 2020 20:26:21

**US3432094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2011'	System	11 Aug 2020 20:26:21

**US3432094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 2012'	System	11 Aug 2020 20:26:21

**US3432094**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2012'	System	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:31:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per MM: Please review and consider capturing CORONARY ARTERY DISEASE and CORONARY STENT USER separately. Update as appropriate.' (Site from DM). Query 'Per MM: Please review and consider capturing CORONARY ARTERY DISEASE and CORONARY STENT USER separately. Update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 08:04:02
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Monica Feeley (b) (4)	15 Sep 2020 22:15:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 22:14:54
Data point term sent to Coder	System	15 Sep 2020 22:13:17
Coding entries removed.	Monica Feeley (b) (4)	15 Sep 2020 22:12:33
User entered 'CORONARY ARTERY DISEASE' reason for change: Per Query Resolution	Monica Feeley (b) (4)	15 Sep 2020 22:12:33
User opened query 'Per MM: Please review and consider capturing CORONARY ARTERY DISEASE and CORONARY STENT USER separately. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:04:16
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 04:02:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 04:02:09
Data point term sent to Coder	System	11 Aug 2020 20:30:24
User entered 'Coronary artery disease w/ stents'	Bruce Bausk (b) (4)	11 Aug 2020 20:29:46



**US3432094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'un Sep 2007'	Bruce Bausk (b) (4)	11 Aug 2020 20:29:46

**US3432094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 20:29:46

**US3432094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	11 Aug 2020 20:29:46

**US3432094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Bruce Bausk (b) (4)	11 Aug 2020 20:29:46

**US3432094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 20:29:46

**US3432094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Sep 2007'	System	11 Aug 2020 20:29:46

**US3432094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2007'	System	11 Aug 2020 20:29:46

**US3432094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 20:29:46



**US3432094**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as SOC: Cardiac disorders, HLT: Cardiac conduction disorders, PT: Atrioventricular block, LLT: Heart block - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:31:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:31:16
Data point term sent to Coder	System	11 Aug 2020 20:30:25
User entered 'Heart block'	Bruce Bausk (b) (4)	11 Aug 2020 20:30:05

**US3432094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'un UNK 2018'	Bruce Bausk (b) (4)	11 Aug 2020 20:30:05

**US3432094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 20:30:05

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:31:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 21:41:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	11 Aug 2020 21:41:37
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 20:30:05
User entered 'No (N)'	Bruce Bausk (b) (4)	11 Aug 2020 20:30:05

**US3432094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Bruce Bausk (b) (4)	11 Aug 2020 20:30:05

**US3432094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Bruce Bausk (b) (4)	11 Aug 2020 20:30:05

**US3432094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 2018'	System	11 Aug 2020 20:30:05



**US3432094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2018'	System	11 Aug 2020 20:30:05

**US3432094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 20:30:05

**US3432094**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 22:15:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 22:15:43
Data point term sent to Coder	System	15 Sep 2020 22:14:18
User entered 'CORONARY STENT'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Start date is after date of Informed System Consent. Please correct.' (Site from System).		15 Sep 2020 22:13:35
User entered 'UN Sep 2007' reason for change: Data Monica Feeley Entry Error	(b) (4)	15 Sep 2020 22:13:35
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	15 Sep 2020 22:13:27
User entered 'UN Sep 2020'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per DM RQ: Thank you for the response. As per response The stent is still in the body. Please update the related medical condition on a separate logline as continuing and update a stop date for the surgical procedure CORONARY STENT. Else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 08:39:22
Query 'Per DM RQ: Thank you for the response. As per response The stent is still in the body. Please update the related medical condition on a separate logline as continuing and update a stop date for the surgical procedure CORONARY STENT. Else clarify.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	04 Dec 2020 14:45:17
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	04 Dec 2020 14:45:13
User opened query 'Per DM RQ: Thank you for the response. As per response The stent is still in the body. Please update the related medical condition on a separate logline as continuing and update a stop date for the surgical procedure CORONARY STENT. Else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 05:52:13
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 05:52:13
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'The stent is still in the body. Thanks.' (Site from DM).	Bruce Bausk (b) (4)	27 Oct 2020 15:27:39
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:55:58

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46
	(b) (4)	



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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Un Sep 2007' reason for change: Data Entry Error	Monica Feeley (b) (4)	04 Dec 2020 14:45:13
User entered empty.	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Sep 2007'	System	15 Sep 2020 22:13:35
User entered 'Sep 2020'	System	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2007'	System	15 Sep 2020 22:13:35
User entered '2020'	System	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Sep 2007'	System	04 Dec 2020 14:45:13
User entered empty.	System	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:31:57

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2007'	System	04 Dec 2020 14:45:13
User entered empty.	System	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:31:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
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)	11 Aug 2020 21:43:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:43:17
Data point term sent to Coder	System	11 Aug 2020 21:42:30
User entered 'Hypertension'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:02

**US3432094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:02



**US3432094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:02

**US3432094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:02

**US3432094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:31:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:42:02

**US3432094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:02

**US3432094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 1990'	System	11 Aug 2020 21:42:02

**US3432094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '1990'	System	11 Aug 2020 21:42:02

**US3432094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 21:42:02

**US3432094**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 21:42:02



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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:31:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:43:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:43:18
Data point term sent to Coder	System	11 Aug 2020 21:42:30
User entered 'Hypothyroidism'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:27

**US3432094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:27

**US3432094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:27

**US3432094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:27

**US3432094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:31:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:42:27

**US3432094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:27

**US3432094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 1990'	System	11 Aug 2020 21:42:27

**US3432094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '1990'	System	11 Aug 2020 21:42:27



**US3432094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 21:42:27

**US3432094**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 21:42:27

US3432094

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:31:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Please confirm if subject is taking any medications for low vit D.' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 22:48:18
Query 'Please confirm if subject is taking any medications for low vit D.' answered with 'per clinician, not taking medications' (Site from CRA).	Monica Feeley (b) (4)	18 Aug 2020 15:01:02
User opened query 'Please confirm if subject is taking any medications for low vit D.' (Site from CRA).	(b) (4), (b) (6)	15 Aug 2020 23:04:23
User coded data point as SOC: Investigations, HLG: Metabolic, nutritional and blood gas investigations, HLT: Vitamin analyses, PT: Vitamin D decreased, LLT: Vitamin D low - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:44:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:44:18
Data point term sent to Coder	System	11 Aug 2020 21:43:31
User entered 'Low vitamin D'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:47

**US3432094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:47

**US3432094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:47

**US3432094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:47

**US3432094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:31:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:42:47

**US3432094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:47



**US3432094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 1990'	System	11 Aug 2020 21:42:47

**US3432094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '1990'	System	11 Aug 2020 21:42:47

**US3432094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 21:42:47

**US3432094**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 21:42:47

US3432094

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:31:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Esophageal reflux - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:44:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:44:18
Data point term sent to Coder	System	11 Aug 2020 21:43:32
User entered 'Esophageal reflux'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:05

**US3432094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:05

**US3432094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:05

**US3432094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:05



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**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:31:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:43:05

**US3432094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:05

**US3432094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 1990'	System	11 Aug 2020 21:43:05

**US3432094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '1990'	System	11 Aug 2020 21:43:05

**US3432094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 21:43:05

**US3432094**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	11 Aug 2020 21:43:05

US3432094

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:31:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:45:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:45:19
Data point term sent to Coder	System	11 Aug 2020 21:44:33
User entered 'Prostate cancer'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:34

**US3432094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UN UNK 2003'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:34



**US3432094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:34

**US3432094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:34

**US3432094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:31:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UN UNK 2003'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:34

**US3432094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:34

**US3432094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 2003'	System	11 Aug 2020 21:43:34

**US3432094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2003'	System	11 Aug 2020 21:43:34

**US3432094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 2003'	System	11 Aug 2020 21:43:34

**US3432094**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2003'	System	11 Aug 2020 21:43:34



US3432094

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:31:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Nervous system neoplasms malignant and unspecified NEC, HLT: Nervous system neoplasms unspecified malignancy NEC, PT: Meningioma, LLT: Meningioma - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:45:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:45:19
Data point term sent to Coder	System	11 Aug 2020 21:44:33
User entered 'Meningioma'	Julia Klopfer (b) (4)	11 Aug 2020 21:44:19

**US3432094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UN Nov 2011'	Julia Klopfer (b) (4)	11 Aug 2020 21:44:19

**US3432094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:44:19

US3432094

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:31:57

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	04 Dec 2020 15:30:00
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:44:19

**US3432094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:31:57**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	04 Dec 2020 15:30:00
User entered 'UN UNK 2012'	Julia Klopfer (b) (4)	11 Aug 2020 21:44:19

**US3432094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:44:19

**US3432094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Nov 2011'	System	11 Aug 2020 21:44:19

**US3432094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2011'	System	11 Aug 2020 21:44:19



**US3432094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	04 Dec 2020 15:30:00
User entered 'Jan 2012'	System	11 Aug 2020 21:44:19

**US3432094**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	04 Dec 2020 15:30:00
User entered '2012'	System	11 Aug 2020 21:44:19

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:31:57

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:00:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:00:24
Data point term sent to Coder	System	18 Aug 2020 14:59:31
User entered 'Depression'	Monica Feeley (b) (4)	18 Aug 2020 14:58:41

**US3432094**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UN UNK 2003'	Monica Feeley (b) (4)	18 Aug 2020 14:58:41

**US3432094**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	18 Aug 2020 14:58:41

**US3432094**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Monica Feeley (b) (4)	18 Aug 2020 14:58:41

**US3432094**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:31:57**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	18 Aug 2020 14:58:41

**US3432094**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	18 Aug 2020 14:58:41



**US3432094**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 2003'	System	18 Aug 2020 14:58:41

**US3432094**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2003'	System	18 Aug 2020 14:58:41

**US3432094**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	18 Aug 2020 14:58:41

**US3432094**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered empty.	System	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:31:57

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:00:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Nervous system therapeutic procedures NEC, PT: Meningioma surgery, LLT: Meningioma surgery - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 09:48:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 09:48:01
Data point term sent to Coder	System	20 Apr 2021 20:43:02
User entered 'surgical resection for meningioma'	Monica Feeley (b) (4)	20 Apr 2021 20:42:54

**US3432094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:00:29
User entered 'UN UNK 2012'	Monica Feeley (b) (4)	20 Apr 2021 20:42:54

**US3432094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:00:29
User entered '0'	Monica Feeley (b) (4)	20 Apr 2021 20:42:54

**US3432094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:00:29
User entered 'No (N)'	Monica Feeley (b) (4)	20 Apr 2021 20:42:54



**US3432094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:31:57**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:00:29
User entered 'UN UNK 2012'	Monica Feeley (b) (4)	20 Apr 2021 20:42:54

**US3432094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:00:29
User entered '0'	Monica Feeley (b) (4)	20 Apr 2021 20:42:54

**US3432094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 2012'	System	20 Apr 2021 20:42:54

**US3432094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2012'	System	20 Apr 2021 20:42:54

**US3432094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'Jan 2012'	System	20 Apr 2021 20:42:54

**US3432094**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '2012'	System	20 Apr 2021 20:42:54

**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33

**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Aug 2020'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33



**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '14:10'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33

**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered '11 Aug 2020 14:10'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '174' cm	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33
DataPoint set to visible.	(b) (4) System	11 Aug 2020 19:14:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '90.6' kg	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33
DataPoint set to visible.	(b) (4) System	11 Aug 2020 19:14:33

**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
Amendment Manager: User entered '29.92469'	System	16 Sep 2020 23:52:01
User entered '29.9'	System	11 Aug 2020 21:46:33
DataPoint set to visible.	System	11 Aug 2020 19:14:33

**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'kg/m2'	System	11 Aug 2020 21:46:33
DataPoint set to visible.	System	11 Aug 2020 19:14:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '37.1' C	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 11:57:29
Query 'Data is required. Please provide.' answered with 'No data is listed per (b) (6) request.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 19:30:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 19:30:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33



**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '60'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33

**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'bpm'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '16'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33

**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'breaths/min'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '135'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33

**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'mmHg'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '66'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33



**US3432094**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User entered 'mmHg'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27

**US3432094**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:31:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:42

US3432094

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 22:46:41
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 14:07:50
User entered '11 Aug 2020'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:42

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

**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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38



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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

[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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

**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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

[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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

**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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38



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Folder: Screening

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Retired physician'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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Folder: Screening

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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'I'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

**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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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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)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:57

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38



**US3432094**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:31:57**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

**US3432094**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 17:31:57**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:36:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:47:38

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:53

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Aug 2020'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:53

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:57

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4)	11 Aug 2020 21:47:53

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'VISIT1'	System	11 Aug 2020 21:47:53

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:57

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:19:34

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:57

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:37:42
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:37:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 18:19:34
User entered '185402' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:19:34



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:57

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:19:34

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:57

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)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:48:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:57

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)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:48:30

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:57

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:48:30

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:31:57**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:48:30

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:57

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:48:30

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:31:57**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:46
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:33:34

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09



US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User accepted default value 'Pre-Dose (PREDOSE)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Aug 2020'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '14:10'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '11 Aug 2020 14:10'	System	11 Aug 2020 21:51:09



US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '37.1' C	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '60'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'bpm'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '16'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'breaths/min'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '135'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '66'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:57

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:57

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User accepted default value 'Post-Dose (POSTDOSE)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Aug 2020'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 10:54:14
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, 30 mins after vaccine' (Site from System).	Julia Klopfer (b) (4)	11 Aug 2020 21:51:27
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	11 Aug 2020 21:51:09
User entered '15:53'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '11 Aug 2020 15:53'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '36.9' C	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '46'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'bpm'	System	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '15'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'breaths/min'	System	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '136'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '64'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	11 Aug 2020 21:51:09

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:33

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:57

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:51:33

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	11 Aug 2020 19:45:55



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Bruce Bausk (b) (4)	11 Aug 2020 19:45:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Bruce Bausk (b) (4)	11 Aug 2020 19:45:55

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**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:57**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:45:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Aug 2020'	Bruce Bausk (b) (4)	11 Aug 2020 19:45:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '15:22'	Bruce Bausk (b) (4)	11 Aug 2020 19:45:55

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**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:57**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '11 Aug 2020 15:22'	System	11 Aug 2020 19:45:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Right Arm (RIGHT ARM)'	Bruce Bausk (b) (4)	11 Aug 2020 19:45:55

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'ONCE'	System	11 Aug 2020 19:45:55



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 22:40:02

US3432094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Aug 2020'	Julia Klopfer (b) (4)	11 Aug 2020 22:40:02

US3432094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:57

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '14:20'	Julia Klopfer (b) (4)	11 Aug 2020 22:40:02

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '11 Aug 2020 14:20'	System	11 Aug 2020 22:40:02

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:31:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Aug 2020'	Julia Klopfer (b) (4)	11 Aug 2020 22:40:19

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:19

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 22:40:19



**US3432094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '14:25'	Julia Klopfer (b) (4)	11 Aug 2020 22:40:19

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '11 Aug 2020 14:25'	System	11 Aug 2020 22:40:19

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:40:19

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:40:19

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered empty.	System	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:56:00

**US3432094**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'I'	System	11 Aug 2020 21:56:00



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:03', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c6bbd1a6-e1dc-4c96-9ef6-7fee289cc805' User entered 'Yes (Y)'	System	11 Aug 2020 20:00:33
	System	11 Aug 2020 20:00:33

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c6bbd1a6-e1dc-4c96-9ef6-7fee289cc805' User entered '98.4'	System	11 Aug 2020 20:00:33
	System	11 Aug 2020 20:00:33

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c6bbd1a6-e1dc-4c96-9ef6-7fee289cc805'	System	11 Aug 2020 20:00:33
User entered 'No (N)'	System	11 Aug 2020 20:00:33

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c6bbd1a6-e1dc-4c96-9ef6-7fee289cc805'	System	11 Aug 2020 20:00:33
User entered '11 Aug 2020 16:00'	System	11 Aug 2020 20:00:33

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Aug 2020 15:42'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Aug 2020 18:12'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:45:55



US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:21:36', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'abf6a8b3-96c7-4d19-97a3-93350feafd33'	System	12 Aug 2020 03:21:54
User entered 'Yes (Y)'	System	12 Aug 2020 03:21:54

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:21:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'abf6a8b3-96c7-4d19-97a3-93350feafd33' User entered '96.3'	System	12 Aug 2020 03:21:54
	System	12 Aug 2020 03:21:54

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:21:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'abf6a8b3-96c7-4d19-97a3-93350feafd33'	System	12 Aug 2020 03:21:54
User entered 'No (N)'	System	12 Aug 2020 03:21:54

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:21:52', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'abf6a8b3-96c7-4d19-97a3-93350feafd33'	System	12 Aug 2020 03:21:54
User entered '11 Aug 2020 23:21'	System	12 Aug 2020 03:21:54

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Aug 2020 19:07'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 2'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:12:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19e8aa87-c133-45ec-9e10-13f20cddec7b' User entered 'Yes (Y)'	System	13 Aug 2020 03:13:01
	System	13 Aug 2020 03:13:01



US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:12:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19e8aa87-c133-45ec-9e10-13f20cddec7b' User entered '96.3'	System	13 Aug 2020 03:13:01
	System	13 Aug 2020 03:13:01

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:12:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19e8aa87-c133-45ec-9e10-13f20cddec7b' User entered 'No (N)'	System	13 Aug 2020 03:13:01
	System	13 Aug 2020 03:13:01

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:00', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19e8aa87-c133-45ec-9e10-13f20cddec7b' User entered '12 Aug 2020 23:13'	System	13 Aug 2020 03:13:01
	System	13 Aug 2020 03:13:01

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 3'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '678b7bc3-8acc-4d0d-b8a4-7a71d81e3d65' User entered 'Yes (Y)'	System	14 Aug 2020 03:16:31
	System	14 Aug 2020 03:16:31

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '678b7bc3-8acc-4d0d-b8a4-7a71d81e3d65' User entered '95.9'	System	14 Aug 2020 03:16:31
	System	14 Aug 2020 03:16:31



US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '678b7bc3-8acc-4d0d-b8a4-7a71d81e3d65' User entered 'No (N)'	System	14 Aug 2020 03:16:31
	System	14 Aug 2020 03:16:31

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '678b7bc3-8acc-4d0d-b8a4-7a71d81e3d65' User entered '13 Aug 2020 23:16'	System	14 Aug 2020 03:16:31
	System	14 Aug 2020 03:16:31

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 4'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:31:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '450f3368-b4b5-43ee-b675-1e1c2f7a524e' User entered 'Yes (Y)'	System	14 Aug 2020 22:31:57
	System	14 Aug 2020 22:31:57

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:31:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '450f3368-b4b5-43ee-b675-1e1c2f7a524e' User entered '96.5'	System	14 Aug 2020 22:31:57
	System	14 Aug 2020 22:31:57

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:31:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '450f3368-b4b5-43ee-b675-1e1c2f7a524e' User entered 'No (N)'	System	14 Aug 2020 22:31:57
	System	14 Aug 2020 22:31:57



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:31:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '450f3368-b4b5-43ee-b675-1e1c2f7a524e' User entered '14 Aug 2020 18:31'	System	14 Aug 2020 22:31:57
	System	14 Aug 2020 22:31:57

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 5'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a9c9b5df-49b4-4f9e-b181-aaaad5b88559' User entered 'Yes (Y)'	System	16 Aug 2020 03:16:45
	System	16 Aug 2020 03:16:45

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a9c9b5df-49b4-4f9e-b181-aaaad5b88559' User entered '96.2'	System	16 Aug 2020 03:16:45
	System	16 Aug 2020 03:16:45

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a9c9b5df-49b4-4f9e-b181-aaaad5b88559'	System	16 Aug 2020 03:16:45
User entered 'No (N)'	System	16 Aug 2020 03:16:45

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a9c9b5df-49b4-4f9e-b181-aaaad5b88559' User entered '15 Aug 2020 23:16'	System	16 Aug 2020 03:16:45
	System	16 Aug 2020 03:16:45



US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 6'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e0bf1b2f-2485-408c-968a-0deb9ee75a4e' User entered 'Yes (Y)'	System	17 Aug 2020 02:58:42
	System	17 Aug 2020 02:58:42

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:33', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e0bf1b2f-2485-408c-968a-0deb9ee75a4e' User entered '96.3'	System	17 Aug 2020 02:58:42
	System	17 Aug 2020 02:58:42

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:36', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e0bf1b2f-2485-408c-968a-0deb9ee75a4e'	System	17 Aug 2020 02:58:42
User entered 'No (N)'	System	17 Aug 2020 02:58:42

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e0bf1b2f-2485-408c-968a-0deb9ee75a4e' User entered '16 Aug 2020 22:58'	System	17 Aug 2020 02:58:42
	System	17 Aug 2020 02:58:42

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:45:55



US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 7'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '426eb8e4-7888-4906-8aae-6165b2082a73' User entered 'Yes (Y)'	System	18 Aug 2020 03:38:32
	System	18 Aug 2020 03:38:32

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '426eb8e4-7888-4906-8aae-6165b2082a73' User entered '97.0'	System	18 Aug 2020 03:38:32
	System	18 Aug 2020 03:38:32

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '426eb8e4-7888-4906-8aae-6165b2082a73'	System	18 Aug 2020 03:38:32
User entered 'No (N)'	System	18 Aug 2020 03:38:32

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '426eb8e4-7888-4906-8aae-6165b2082a73'	System	18 Aug 2020 03:38:32
User entered '17 Aug 2020 23:38'	System	18 Aug 2020 03:38:32

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:45:55



US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:47', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered 'None (1)'	System	11 Aug 2020 20:01:20

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered 'No (N)'	System	11 Aug 2020 20:01:20

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:58', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered 'No (N)'	System	11 Aug 2020 20:01:20

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered 'None (1)'	System	11 Aug 2020 20:01:20

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered '11 Aug 2020 16:01'	System	11 Aug 2020 20:01:20

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Aug 2020 15:42'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Aug 2020 18:12'	System	11 Aug 2020 19:45:55



US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:03', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0'	System	12 Aug 2020 03:22:37
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 03:22:37

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:07', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0' User entered 'No (N)'	System	12 Aug 2020 03:22:37
	System	12 Aug 2020 03:22:37

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:10', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0' User entered 'No (N)'	System	12 Aug 2020 03:22:37
	System	12 Aug 2020 03:22:37

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0'	System	12 Aug 2020 03:22:37
User entered 'None (1)'	System	12 Aug 2020 03:22:37

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0'	System	12 Aug 2020 03:22:37
User entered '11 Aug 2020 23:22'	System	12 Aug 2020 03:22:37

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Aug 2020 19:07'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:45:55



US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 2'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511'	System	13 Aug 2020 03:14:26
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511'	System	13 Aug 2020 03:14:26
User entered 'No (N)'	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:29', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511' User entered 'Yes (Y)'	System	13 Aug 2020 03:14:26
	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511' User entered '50'	System	13 Aug 2020 03:14:26
	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511'	System	13 Aug 2020 03:14:26
User entered 'None (1)'	System	13 Aug 2020 03:14:26

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511' User entered '12 Aug 2020 23:14'	System	13 Aug 2020 03:14:26
	System	13 Aug 2020 03:14:26

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:45:55



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 3'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66'	System	14 Aug 2020 03:17:19
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66'	System	14 Aug 2020 03:17:19
User entered 'No (N)'	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66' User entered 'Yes (Y)'	System	14 Aug 2020 03:17:19
	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66' User entered '20'	System	14 Aug 2020 03:17:19
	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:08', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66'	System	14 Aug 2020 03:17:19
User entered 'None (1)'	System	14 Aug 2020 03:17:19

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66'	System	14 Aug 2020 03:17:19
User entered '13 Aug 2020 23:17'	System	14 Aug 2020 03:17:19



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 4'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b' User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 22:32:41
	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:05', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b' User entered 'No (N)'	System	14 Aug 2020 22:32:41
	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:09', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b' User entered 'Yes (Y)'	System	14 Aug 2020 22:32:41
	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b' User entered '15'	System	14 Aug 2020 22:32:41
	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b' User entered 'None (1)'	System	14 Aug 2020 22:32:41
	System	14 Aug 2020 22:32:41



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b' User entered '14 Aug 2020 18:32'	System	14 Aug 2020 22:32:41
	System	14 Aug 2020 22:32:41

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 5'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952'	System	16 Aug 2020 03:17:11
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 03:17:11

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952'	System	16 Aug 2020 03:17:11
User entered 'No (N)'	System	16 Aug 2020 03:17:11

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952' User entered 'Yes (Y)'	System	16 Aug 2020 03:17:11
	System	16 Aug 2020 03:17:11

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952' User entered '10'	System	16 Aug 2020 03:17:11
	System	16 Aug 2020 03:17:11



US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:05', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952'	System	16 Aug 2020 03:17:11
User entered 'None (1)'	System	16 Aug 2020 03:17:11

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:08', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952'	System	16 Aug 2020 03:17:11
User entered '15 Aug 2020 23:17'	System	16 Aug 2020 03:17:11

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 6'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5'	System	17 Aug 2020 02:59:06
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5' User entered 'No (N)'	System	17 Aug 2020 02:59:06
	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5' User entered 'No (N)'	System	17 Aug 2020 02:59:06
	System	17 Aug 2020 02:59:06



US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:01', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5'	System	17 Aug 2020 02:59:06
User entered 'None (1)'	System	17 Aug 2020 02:59:06

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:04', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5' User entered '16 Aug 2020 22:59'	System	17 Aug 2020 02:59:06
	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 7'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:36', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014'	System	18 Aug 2020 03:38:51
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 03:38:51

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014' User entered 'No (N)'	System	18 Aug 2020 03:38:51
	System	18 Aug 2020 03:38:51

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014' User entered 'No (N)'	System	18 Aug 2020 03:38:51
	System	18 Aug 2020 03:38:51



US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014'	System	18 Aug 2020 03:38:51
User entered 'None (1)'	System	18 Aug 2020 03:38:51

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014' User entered '17 Aug 2020 23:38'	System	18 Aug 2020 03:38:51
	System	18 Aug 2020 03:38:51

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1' User entered 'None (0)'	System	11 Aug 2020 20:01:59
	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1' User entered 'None (0)'	System	11 Aug 2020 20:01:59
	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1' User entered 'None (0)'	System	11 Aug 2020 20:01:59
	System	11 Aug 2020 20:01:59



US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1' User entered 'None (0)'	System	11 Aug 2020 20:01:59
	System	11 Aug 2020 20:01:59

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1' User entered 'None (0)'	System	11 Aug 2020 20:01:59
	System	11 Aug 2020 20:01:59

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1' User entered 'None (0)'	System	11 Aug 2020 20:01:59
	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1' User entered 'No (N)'	System	11 Aug 2020 20:01:59
	System	11 Aug 2020 20:01:59

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1' User entered '11 Aug 2020 16:01'	System	11 Aug 2020 20:01:59
	System	11 Aug 2020 20:01:59

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Aug 2020 15:42'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Aug 2020 18:12'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:45:55



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52' User entered 'None (0)'	System	12 Aug 2020 03:23:28
	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:23:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered 'No interference with activity (1)'	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52' User entered 'None (0)'	System	12 Aug 2020 03:23:28
	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52' User entered 'None (0)'	System	12 Aug 2020 03:23:28
	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:59', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52' User entered 'None (0)'	System	12 Aug 2020 03:23:28
	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:23:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52' User entered 'None (0)'	System	12 Aug 2020 03:23:28
	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:23:07', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered 'No (N)'	System	12 Aug 2020 03:23:28

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:23:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered '11 Aug 2020 23:23'	System	12 Aug 2020 03:23:28



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Aug 2020 19:07'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 2'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2' User entered 'None (0)'	System	13 Aug 2020 03:15:16
	System	13 Aug 2020 03:15:16

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered 'No interference with activity (1)'	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2' User entered 'None (0)'	System	13 Aug 2020 03:15:16
	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:47', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2' User entered 'None (0)'	System	13 Aug 2020 03:15:16
	System	13 Aug 2020 03:15:16

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2' User entered 'None (0)'	System	13 Aug 2020 03:15:16
	System	13 Aug 2020 03:15:16



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2' User entered 'None (0)'	System	13 Aug 2020 03:15:16
	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered 'No (N)'	System	13 Aug 2020 03:15:16

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:15:10', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered '12 Aug 2020 23:15'	System	13 Aug 2020 03:15:16

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 3'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7' User entered 'None (0)'	System	14 Aug 2020 03:17:59
	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7' User entered 'None (0)'	System	14 Aug 2020 03:17:59
	System	14 Aug 2020 03:17:59



US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7' User entered 'None (0)'	System	14 Aug 2020 03:17:59
	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7' User entered 'None (0)'	System	14 Aug 2020 03:17:59
	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7'	System	14 Aug 2020 03:17:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	14 Aug 2020 03:17:59

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7' User entered 'None (0)'	System	14 Aug 2020 03:17:59
	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7' User entered 'No (N)'	System	14 Aug 2020 03:17:59
	System	14 Aug 2020 03:17:59

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7' User entered '13 Aug 2020 23:17'	System	14 Aug 2020 03:17:59
	System	14 Aug 2020 03:17:59

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:45:55



US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 4'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c' User entered 'None (0)'	System	14 Aug 2020 22:33:01
	System	14 Aug 2020 22:33:01

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c' User entered 'None (0)'	System	14 Aug 2020 22:33:01
	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c' User entered 'None (0)'	System	14 Aug 2020 22:33:01
	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c' User entered 'None (0)'	System	14 Aug 2020 22:33:01
	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:51', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c' User entered 'None (0)'	System	14 Aug 2020 22:33:01
	System	14 Aug 2020 22:33:01

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c' User entered 'None (0)'	System	14 Aug 2020 22:33:01
	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c' User entered 'No (N)'	System	14 Aug 2020 22:33:01
	System	14 Aug 2020 22:33:01



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:59', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c' User entered '14 Aug 2020 18:32'	System	14 Aug 2020 22:33:01
	System	14 Aug 2020 22:33:01

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 5'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:14', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc' User entered 'None (0)'	System	16 Aug 2020 03:17:35
	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc' User entered 'None (0)'	System	16 Aug 2020 03:17:35
	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc' User entered 'None (0)'	System	16 Aug 2020 03:17:35
	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc' User entered 'None (0)'	System	16 Aug 2020 03:17:35
	System	16 Aug 2020 03:17:35



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc' User entered 'None (0)'	System	16 Aug 2020 03:17:35
	System	16 Aug 2020 03:17:35

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc' User entered 'None (0)'	System	16 Aug 2020 03:17:35
	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc' User entered 'No (N)'	System	16 Aug 2020 03:17:35
	System	16 Aug 2020 03:17:35

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc' User entered '15 Aug 2020 23:17'	System	16 Aug 2020 03:17:35
	System	16 Aug 2020 03:17:35

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 6'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:08', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143' User entered 'None (0)'	System	17 Aug 2020 02:59:31
	System	17 Aug 2020 02:59:31



US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:11', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143' User entered 'None (0)'	System	17 Aug 2020 02:59:31
	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:14', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143' User entered 'None (0)'	System	17 Aug 2020 02:59:31
	System	17 Aug 2020 02:59:31

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143' User entered 'None (0)'	System	17 Aug 2020 02:59:31
	System	17 Aug 2020 02:59:31

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143' User entered 'None (0)'	System	17 Aug 2020 02:59:31
	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143' User entered 'None (0)'	System	17 Aug 2020 02:59:31
	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143' User entered 'No (N)'	System	17 Aug 2020 02:59:31
	System	17 Aug 2020 02:59:31

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143' User entered '16 Aug 2020 22:59'	System	17 Aug 2020 02:59:31
	System	17 Aug 2020 02:59:31

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:45:55



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 7'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71' User entered 'None (0)'	System	18 Aug 2020 03:39:16
	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:55', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71' User entered 'None (0)'	System	18 Aug 2020 03:39:16
	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:58', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71' User entered 'None (0)'	System	18 Aug 2020 03:39:16
	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:01', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71' User entered 'None (0)'	System	18 Aug 2020 03:39:16
	System	18 Aug 2020 03:39:16

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:03', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71' User entered 'None (0)'	System	18 Aug 2020 03:39:16
	System	18 Aug 2020 03:39:16

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:05', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71' User entered 'None (0)'	System	18 Aug 2020 03:39:16
	System	18 Aug 2020 03:39:16



US3432094

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:10', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71' User entered 'No (N)'	System	18 Aug 2020 03:39:16
	System	18 Aug 2020 03:39:16

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71' User entered '17 Aug 2020 23:39'	System	18 Aug 2020 03:39:16
	System	18 Aug 2020 03:39:16

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	17 Aug 2020 02:59:06
User entered 'Day 8'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-18T23:19:14', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7dd8427f-ab71-4c8e-891c-79995f430dea' User entered 'None (1)'	System	19 Aug 2020 03:19:19
	System	19 Aug 2020 03:19:19

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-18T23:19:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7dd8427f-ab71-4c8e-891c-79995f430dea' User entered '18 Aug 2020 23:19'	System	19 Aug 2020 03:19:19
	System	19 Aug 2020 03:19:19

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 02:59:06



**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 02:59:06

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	17 Aug 2020 02:59:06
User entered 'Day 8'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-18T23:19:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43f0ed70-624a-4c54-b67d-af517168e51b' User entered 'No (N)'	System	19 Aug 2020 03:19:29
	System	19 Aug 2020 03:19:29

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-18T23:19:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43f0ed70-624a-4c54-b67d-af517168e51b' User entered '18 Aug 2020 23:19'	System	19 Aug 2020 03:19:29
	System	19 Aug 2020 03:19:29

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 02:59:06

**US3432094**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 02:59:06

**US3432094**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:45

**US3432094**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '18 Aug 2020'	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:45



**US3432094**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:45

US3432094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:57

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:45

US3432094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:53

**US3432094**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'I'	System	18 Aug 2020 15:15:53

**US3432094**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:52

US3432094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '25 Aug 2020'	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:52

**US3432094**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:52

US3432094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:57

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:52



US3432094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:56

**US3432094**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'I'	System	25 Aug 2020 16:47:56

**US3432094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:03

**US3432094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '1 Sep 2020'	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:03

**US3432094**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:03

US3432094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:57

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:03

US3432094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:07

**US3432094**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'I'	System	01 Sep 2020 17:16:07



**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:07:50

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:07:50

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Sep 2020 14:07:50

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'VISIT2'	System	10 Sep 2020 14:07:50

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '9:06'	(b) (4), (b) (6)	10 Sep 2020 14:58:21



**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '10 Sep 2020 9:06'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '98.1' F	(b) (4), (b) (6)	10 Sep 2020 14:58:21

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '53'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'bpm'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '14'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'breaths/min'	System	10 Sep 2020 14:58:21



US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '142'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '64'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 14:58:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Sep 2020 14:58:57
User entered '10:35' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:58:57
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 14:58:21
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:58:21



**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '10 Sep 2020 10:35'	System	10 Sep 2020 14:58:57
User entered empty.	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '97.9' F	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:31:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '48'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'bpm'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '18'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'breaths/min'	System	10 Sep 2020 14:58:21



US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '146'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '67'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	10 Sep 2020 14:58:21

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:31:57**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:08:03

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:31:57**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:08:03

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:57**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:30:06

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:57**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:30:06



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:30:06

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:57**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:30:06

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:57**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '10:05'	(b) (4), (b) (6)	10 Sep 2020 14:30:06

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:57**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '10 Sep 2020 10:05'	System	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	10 Sep 2020 14:30:15
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	10 Sep 2020 14:30:15
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:30:15
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	10 Sep 2020 14:30:06
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:57

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'ONCE'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:31:57**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 14:30:06



**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:51:33

US3432094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 10SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 10SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:14:19
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 10SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 10SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' answered with 'Updated on PPD.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 14:50:55
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 10SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 10SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:25:14
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:51:33

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '9:50'	(b) (4), (b) (6)	10 Sep 2020 14:51:33

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '10 Sep 2020 9:50'	System	10 Sep 2020 14:51:33

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:31:57

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 11:52:40
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Updated on PPD.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 14:50:46
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:49:15
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '10:00'	(b) (4), (b) (6)	10 Sep 2020 14:51:57



US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:57

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 11:08:32
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:11:06
User entered '10 Sep 2020 10:00'	System	10 Sep 2020 14:51:57

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:51:57

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered empty.	System	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:30:22

**US3432094**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '1'	System	10 Sep 2020 14:30:22

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:30:06



US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:15', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '342f4d23-6d24-434a-82d6-7412636bb12b' User entered 'Yes (Y)'	System	10 Sep 2020 14:42:36
	System	10 Sep 2020 14:42:36

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '342f4d23-6d24-434a-82d6-7412636bb12b' User entered '97.9'	System	10 Sep 2020 14:42:36
	System	10 Sep 2020 14:42:36

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '342f4d23-6d24-434a-82d6-7412636bb12b' User entered 'No (N)'	System	10 Sep 2020 14:42:36
	System	10 Sep 2020 14:42:36

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '342f4d23-6d24-434a-82d6-7412636bb12b' User entered '10 Sep 2020 10:42'	System	10 Sep 2020 14:42:36
	System	10 Sep 2020 14:42:36

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '10 Sep 2020 10:25'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:44:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ea72b43e-1346-4580-b133-8be866113d81' User entered 'Yes (Y)'	System	11 Sep 2020 01:44:56
	System	11 Sep 2020 01:44:56



US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:44:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ea72b43e-1346-4580-b133-8be866113d81' User entered '97.6'	System	11 Sep 2020 01:44:56
	System	11 Sep 2020 01:44:56

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:44:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ea72b43e-1346-4580-b133-8be866113d81'	System	11 Sep 2020 01:44:56
User entered 'No (N)'	System	11 Sep 2020 01:44:56

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:44:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ea72b43e-1346-4580-b133-8be866113d81'	System	11 Sep 2020 01:44:56
User entered '10 Sep 2020 21:44'	System	11 Sep 2020 01:44:56

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '10 Sep 2020 13:50'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 2'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:36:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713' User entered 'Yes (Y)'	System	11 Sep 2020 22:37:31
	System	11 Sep 2020 22:37:31

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713' User entered '98.3'	System	11 Sep 2020 22:37:31
	System	11 Sep 2020 22:37:31



US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713' User entered 'Yes (Y)'	System	11 Sep 2020 22:37:31
	System	11 Sep 2020 22:37:31

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 06:00:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713' User entered '1'	Jun Bai Park Chang (b) (4)	05 Oct 2020 14:09:34
	System	11 Sep 2020 22:37:31
	System	11 Sep 2020 22:37:31
	System	11 Sep 2020 22:37:31

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713' User entered '0'	System	11 Sep 2020 22:37:31
	System	11 Sep 2020 22:37:31

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713' User entered '11 Sep 2020 18:37'	System	11 Sep 2020 22:37:31
	System	11 Sep 2020 22:37:31

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 3'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:18', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37' User entered 'Yes (Y)'	System	13 Sep 2020 02:29:45
	System	13 Sep 2020 02:29:45



US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37' User entered '97.3'	System	13 Sep 2020 02:29:45
	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37'	System	13 Sep 2020 02:29:45
User entered 'Yes (Y)'	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 06:00:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37' User entered '1'	Jun Bai Park Chang (b) (4)	05 Oct 2020 14:09:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 02:29:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37' User entered '1'	System	13 Sep 2020 02:29:45
User entered '1'	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37' User entered '0'	System	13 Sep 2020 02:29:45
	System	13 Sep 2020 02:29:45

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37'	System	13 Sep 2020 02:29:45
User entered '12 Sep 2020 22:29'	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 4'	System	10 Sep 2020 14:30:06



US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:05:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3a402447-bd9e-4025-b4e7-6111ce357b49' User entered 'Yes (Y)'	System	14 Sep 2020 04:06:23
	System	14 Sep 2020 04:06:23

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:06:00', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3a402447-bd9e-4025-b4e7-6111ce357b49' User entered '96.8'	System	14 Sep 2020 04:06:23
	System	14 Sep 2020 04:06:23

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:06:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3a402447-bd9e-4025-b4e7-6111ce357b49' User entered 'No (N)'	System	14 Sep 2020 04:06:23
	System	14 Sep 2020 04:06:23

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:06:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3a402447-bd9e-4025-b4e7-6111ce357b49' User entered '14 Sep 2020 00:06'	System	14 Sep 2020 04:06:23
	System	14 Sep 2020 04:06:23

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 5'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:10:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c0b941ea-79cc-4831-b94b-0069127d6959' User entered 'Yes (Y)'	System	15 Sep 2020 02:10:33
	System	15 Sep 2020 02:10:33



US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:10:21', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c0b941ea-79cc-4831-b94b-0069127d6959' User entered '97.8'	System	15 Sep 2020 02:10:33
	System	15 Sep 2020 02:10:33

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:10:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c0b941ea-79cc-4831-b94b-0069127d6959' User entered 'No (N)'	System	15 Sep 2020 02:10:33
	System	15 Sep 2020 02:10:33

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:10:29', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c0b941ea-79cc-4831-b94b-0069127d6959' User entered '14 Sep 2020 22:10'	System	15 Sep 2020 02:10:33
	System	15 Sep 2020 02:10:33

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 6'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'df380143-4c17-4347-aed0-c33e8ae3dc6b' User entered 'Yes (Y)'	System	16 Sep 2020 01:53:35
	System	16 Sep 2020 01:53:35

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'df380143-4c17-4347-aed0-c33e8ae3dc6b' User entered '97.5'	System	16 Sep 2020 01:53:35
	System	16 Sep 2020 01:53:35



US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'df380143-4c17-4347-aed0-c33e8ae3dc6b' User entered 'No (N)'	System	16 Sep 2020 01:53:35
	System	16 Sep 2020 01:53:35

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'df380143-4c17-4347-aed0-c33e8ae3dc6b' User entered '15 Sep 2020 21:53'	System	16 Sep 2020 01:53:35
	System	16 Sep 2020 01:53:35

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 7'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'eea553bd-618f-4546-a2ca-a86230639499' User entered 'Yes (Y)'	System	17 Sep 2020 04:20:37
	System	17 Sep 2020 04:20:37

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'eea553bd-618f-4546-a2ca-a86230639499' User entered '96.9'	System	17 Sep 2020 04:20:37
	System	17 Sep 2020 04:20:37

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'eea553bd-618f-4546-a2ca-a86230639499'	System	17 Sep 2020 04:20:37
User entered 'No (N)'	System	17 Sep 2020 04:20:37



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'eea553bd-618f-4546-a2ca-a86230639499' User entered '17 Sep 2020 00:20'	System	17 Sep 2020 04:20:37
	System	17 Sep 2020 04:20:37

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a' User entered 'None (1)'	System	10 Sep 2020 14:43:24
	System	10 Sep 2020 14:43:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:52', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a' User entered 'No (N)'	System	10 Sep 2020 14:43:24
	System	10 Sep 2020 14:43:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a' User entered 'No (N)'	System	10 Sep 2020 14:43:24
	System	10 Sep 2020 14:43:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:18', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a' User entered 'None (1)'	System	10 Sep 2020 14:43:24
	System	10 Sep 2020 14:43:24



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:21', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a' User entered '10 Sep 2020 10:43'	System	10 Sep 2020 14:43:24
	System	10 Sep 2020 14:43:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '10 Sep 2020 10:25'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0'	System	11 Sep 2020 01:45:36
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 01:45:36

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0' User entered 'No (N)'	System	11 Sep 2020 01:45:36
	System	11 Sep 2020 01:45:36

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:09', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0' User entered 'Yes (Y)'	System	11 Sep 2020 01:45:36
	System	11 Sep 2020 01:45:36

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0' User entered '15'	System	11 Sep 2020 01:45:36
	System	11 Sep 2020 01:45:36



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0' User entered 'None (1)'	System	11 Sep 2020 01:45:36
	System	11 Sep 2020 01:45:36

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:33', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0' User entered '10 Sep 2020 21:45'	System	11 Sep 2020 01:45:36
	System	11 Sep 2020 01:45:36

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '10 Sep 2020 13:50'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 2'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3'	System	11 Sep 2020 22:38:51
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		11 Sep 2020 22:38:51

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3' User entered 'No (N)'	System	11 Sep 2020 22:38:51
	System	11 Sep 2020 22:38:51

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:48', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3' User entered 'Yes (Y)'	System	11 Sep 2020 22:38:51
	System	11 Sep 2020 22:38:51



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:38:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3' User entered '30'	System	11 Sep 2020 22:38:51
	System	11 Sep 2020 22:38:51

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:38:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3'	System	11 Sep 2020 22:38:51
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 22:38:51

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:38:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3' User entered '11 Sep 2020 18:38'	System	11 Sep 2020 22:38:51
	System	11 Sep 2020 22:38:51

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 3'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb' User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'	System	13 Sep 2020 02:30:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb' User entered 'No (N)'	System	13 Sep 2020 02:30:59
	System	13 Sep 2020 02:30:59



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb' User entered 'Yes (Y)'	System	13 Sep 2020 02:30:59
	System	13 Sep 2020 02:30:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb' User entered '40'	System	13 Sep 2020 02:30:59
	System	13 Sep 2020 02:30:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb'	System	13 Sep 2020 02:30:59
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 02:30:59

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb' User entered '12 Sep 2020 22:30'	System	13 Sep 2020 02:30:59
	System	13 Sep 2020 02:30:59

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 4'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a'	System	14 Sep 2020 04:00:57
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		14 Sep 2020 04:00:57



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:11', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a'	System	14 Sep 2020 04:00:57
User entered 'Yes (Y)'	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a' User entered '50'	System	14 Sep 2020 04:00:57
	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a'	System	14 Sep 2020 04:00:57
User entered 'Yes (Y)'	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a' User entered '50'	System	14 Sep 2020 04:00:57
	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:48', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a'	System	14 Sep 2020 04:00:57
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 04:00:57

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:52', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a' User entered '14 Sep 2020 00:00'	System	14 Sep 2020 04:00:57
	System	14 Sep 2020 04:00:57

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:30:06



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 5'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784'	System	15 Sep 2020 02:12:24
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784' User entered 'Yes (Y)'	System	15 Sep 2020 02:12:24
	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784' User entered '50'	System	15 Sep 2020 02:12:24
	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784' User entered 'Yes (Y)'	System	15 Sep 2020 02:12:24
	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784' User entered '40'	System	15 Sep 2020 02:12:24
	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784'	System	15 Sep 2020 02:12:24
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 02:12:24

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784' User entered '14 Sep 2020 22:12'	System	15 Sep 2020 02:12:24
	System	15 Sep 2020 02:12:24



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 6'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:54:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered 'Yes (Y)'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:54:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456' User entered '40'	System	16 Sep 2020 01:55:45
	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:54:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456' User entered 'Yes (Y)'	System	16 Sep 2020 01:55:45
	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered '40'	System	16 Sep 2020 01:55:45



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 01:55:45

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456' User entered '15 Sep 2020 21:55'	System	16 Sep 2020 01:55:45
	System	16 Sep 2020 01:55:45

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 7'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc'	System	17 Sep 2020 04:21:22
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc' User entered 'No (N)'	System	17 Sep 2020 04:21:22
	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc' User entered 'Yes (Y)'	System	17 Sep 2020 04:21:22
	System	17 Sep 2020 04:21:22



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc' User entered '15'	System	17 Sep 2020 04:21:22
	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc' User entered 'None (1)'	System	17 Sep 2020 04:21:22
	System	17 Sep 2020 04:21:22

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc' User entered '17 Sep 2020 00:21'	System	17 Sep 2020 04:21:22
	System	17 Sep 2020 04:21:22

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48



US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:36', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'No (N)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:45', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered '10 Sep 2020 10:43'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '10 Sep 2020 10:25'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 14:30:06



US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298' User entered 'None (0)'	System	11 Sep 2020 01:46:07
	System	11 Sep 2020 01:46:07

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered 'No interference with activity (1)'	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:45', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298' User entered 'None (0)'	System	11 Sep 2020 01:46:07
	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298' User entered 'None (0)'	System	11 Sep 2020 01:46:07
	System	11 Sep 2020 01:46:07

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:51', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298' User entered 'None (0)'	System	11 Sep 2020 01:46:07
	System	11 Sep 2020 01:46:07

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298' User entered 'None (0)'	System	11 Sep 2020 01:46:07
	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:58', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered 'No (N)'	System	11 Sep 2020 01:46:07



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:46:01', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered '10 Sep 2020 21:46'	System	11 Sep 2020 01:46:07

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '10 Sep 2020 13:50'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 2'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:38:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'Some interference with activity (2)'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609' User entered 'None (0)'	System	11 Sep 2020 22:39:28
	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:09', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609' User entered 'None (0)'	System	11 Sep 2020 22:39:28
	System	11 Sep 2020 22:39:28



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609' User entered 'None (0)'	System	11 Sep 2020 22:39:28
	System	11 Sep 2020 22:39:28

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609' User entered 'None (0)'	System	11 Sep 2020 22:39:28
	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'No (N)'	System	11 Sep 2020 22:39:28

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609' User entered '11 Sep 2020 18:39'	System	11 Sep 2020 22:39:28
	System	11 Sep 2020 22:39:28

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 3'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c' User entered 'None (0)'	System	13 Sep 2020 02:31:33
	System	13 Sep 2020 02:31:33



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c' User entered 'Some interference with activity (2)'	System	13 Sep 2020 02:31:33
	System	13 Sep 2020 02:31:33

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c' User entered 'None (0)'	System	13 Sep 2020 02:31:33
	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c' User entered 'None (0)'	System	13 Sep 2020 02:31:33
	System	13 Sep 2020 02:31:33

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c' User entered 'None (0)'	System	13 Sep 2020 02:31:33
	System	13 Sep 2020 02:31:33

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c' User entered 'None (0)'	System	13 Sep 2020 02:31:33
	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c' User entered 'No (N)'	System	13 Sep 2020 02:31:33
	System	13 Sep 2020 02:31:33

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c' User entered '12 Sep 2020 22:31'	System	13 Sep 2020 02:31:33
	System	13 Sep 2020 02:31:33

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:30:06



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 4'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:00', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered 'No interference with activity (1)'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:07', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered 'Significant; prevents daily activity (3)'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:11', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e' User entered 'None (0)'	System	14 Sep 2020 04:01:30
	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:14', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e' User entered 'None (0)'	System	14 Sep 2020 04:01:30
	System	14 Sep 2020 04:01:30

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e' User entered 'None (0)'	System	14 Sep 2020 04:01:30
	System	14 Sep 2020 04:01:30

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e' User entered 'None (0)'	System	14 Sep 2020 04:01:30
	System	14 Sep 2020 04:01:30



US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e' User entered 'No (N)'	System	14 Sep 2020 04:01:30
	System	14 Sep 2020 04:01:30

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e' User entered '14 Sep 2020 00:01'	System	14 Sep 2020 04:01:30
	System	14 Sep 2020 04:01:30

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 5'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a' User entered 'None (0)'	System	15 Sep 2020 02:12:50
	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a'	System	15 Sep 2020 02:12:50
User entered 'Some interference with activity (2)'	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a' User entered 'None (0)'	System	15 Sep 2020 02:12:50
	System	15 Sep 2020 02:12:50



US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a' User entered 'None (0)'	System	15 Sep 2020 02:12:50
	System	15 Sep 2020 02:12:50

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a' User entered 'None (0)'	System	15 Sep 2020 02:12:50
	System	15 Sep 2020 02:12:50

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a' User entered 'None (0)'	System	15 Sep 2020 02:12:50
	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a' User entered 'No (N)'	System	15 Sep 2020 02:12:50
	System	15 Sep 2020 02:12:50

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:45', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a' User entered '14 Sep 2020 22:12'	System	15 Sep 2020 02:12:50
	System	15 Sep 2020 02:12:50

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 6'	System	10 Sep 2020 14:30:06



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:45', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f' User entered 'None (0)'	System	16 Sep 2020 01:56:09
	System	16 Sep 2020 01:56:09

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f' User entered 'No interference with activity (1)'	System	16 Sep 2020 01:56:09
	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f' User entered 'None (0)'	System	16 Sep 2020 01:56:09
	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f' User entered 'None (0)'	System	16 Sep 2020 01:56:09
	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:58', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f' User entered 'None (0)'	System	16 Sep 2020 01:56:09
	System	16 Sep 2020 01:56:09

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:56:00', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f' User entered 'None (0)'	System	16 Sep 2020 01:56:09
	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:56:03', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f' User entered 'No (N)'	System	16 Sep 2020 01:56:09
	System	16 Sep 2020 01:56:09

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:56:04', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f' User entered '15 Sep 2020 21:56'	System	16 Sep 2020 01:56:09
	System	16 Sep 2020 01:56:09



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 7'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered 'None (0)'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered 'No interference with activity (1)'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered 'None (0)'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered 'None (0)'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered 'None (0)'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered 'None (0)'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered 'No (N)'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered '17 Sep 2020 00:21'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	16 Sep 2020 01:55:45
User entered 'Day 8'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:09:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '238bb030-e062-4d6f-ad2f-0f5f8c27f0df' User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 00:09:43
	System	18 Sep 2020 00:09:43

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:09:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '238bb030-e062-4d6f-ad2f-0f5f8c27f0df' User entered '17 Sep 2020 20:09'	System	18 Sep 2020 00:09:43
	System	18 Sep 2020 00:09:43



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:55:45

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(9)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	17 Sep 2020 04:21:22
User entered 'Day 9'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(9)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(9)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(9)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 04:21:22

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(9)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(10)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	18 Sep 2020 00:09:43
User entered 'Day 10'	System	18 Sep 2020 00:09:43



US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(10)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(10)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(10)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 00:09:43

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(10)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 00:09:43

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	16 Sep 2020 01:55:45
User entered 'Day 8'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6f64ed98-1be6-4334-ba99-c0224f463fcf' User entered 'Yes (Y)'	System	18 Sep 2020 00:10:25
	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(8)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6f64ed98-1be6-4334-ba99-c0224f463fcf' User entered '10'	System	18 Sep 2020 00:10:25
	System	18 Sep 2020 00:10:25

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:21', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6f64ed98-1be6-4334-ba99-c0224f463fcf' User entered '17 Sep 2020 20:10'	System	18 Sep 2020 00:10:25
	System	18 Sep 2020 00:10:25



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:55:45

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(9)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	17 Sep 2020 04:21:22
User entered 'Day 9'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(9)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(9)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(9)

Generated On: 09 Jun 2021 17:31:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(9)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 04:21:22

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Swelling\_Day(9)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 04:21:22



US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(10)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	18 Sep 2020 00:10:25
User entered 'Day 10'	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(10)

Generated On: 09 Jun 2021 17:31:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(10)

Generated On: 09 Jun 2021 17:31:57

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(10)

Generated On: 09 Jun 2021 17:31:57

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(10)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling\_Day(10)

Generated On: 09 Jun 2021 17:31:57

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	16 Sep 2020 01:56:09
User entered 'Day 8'	System	16 Sep 2020 01:56:09

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:29', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5a69b1cf-8911-438b-8335-d776b8778cb8' User entered 'None (0)'	System	18 Sep 2020 00:10:34
	System	18 Sep 2020 00:10:34



**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5a69b1cf-8911-438b-8335-d776b8778cb8' User entered '17 Sep 2020 20:10'	System	18 Sep 2020 00:10:34
	System	18 Sep 2020 00:10:34

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:56:09

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	16 Sep 2020 01:55:45
User entered 'Day 8'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '2dca7b66-888c-41d3-a9fd-1e1b373f3460' User entered 'No (N)'	System	18 Sep 2020 00:10:40
	System	18 Sep 2020 00:10:40

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '2dca7b66-888c-41d3-a9fd-1e1b373f3460'	System	18 Sep 2020 00:10:40
User entered '17 Sep 2020 20:10'	System	18 Sep 2020 00:10:40

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:55:45

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:55:45



US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:31:57

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	17 Sep 2020 04:21:22
User entered 'Day 9'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 04:21:22

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 04:21:22

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	18 Sep 2020 00:09:43
User entered 'Day 10'	System	18 Sep 2020 00:09:43

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:31:57

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 18:26:14

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14



US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 17:31:57

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 00:09:43

**US3432094**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 09 Jun 2021 17:31:57**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 00:09:43

**US3432094**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 17:13:49

**US3432094**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '17 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 17:13:49

**US3432094**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 17:13:49

US3432094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:57

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 17:13:49

US3432094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 17:13:56

**US3432094**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'I'	System	24 Sep 2020 17:13:56



**US3432094**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 17:15:03

**US3432094**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 17:15:03

**US3432094**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 17:15:03

**US3432094**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 17:15:03

**US3432094**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:14:35

**US3432094**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'I'	System	01 Oct 2020 14:14:35

**US3432094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:17:08

**US3432094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 14:17:08



**US3432094**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 14:17:08

US3432094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:57

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 14:17:08

US3432094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:17:12

**US3432094**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'I'	System	01 Oct 2020 14:17:12

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:40:54

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:40:54

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Oct 2020 17:40:54

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'VISIT3'	System	08 Oct 2020 17:40:54



US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '09:54'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '8 Oct 2020 09:54'	System	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '037.0' C	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 17:41:37

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '047'	(b) (4), (b) (6)	08 Oct 2020 17:41:37



**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'bpm'	System	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '014'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'breaths/min'	System	08 Oct 2020 17:41:37

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '136'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '067'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'mmHg'	System	08 Oct 2020 17:41:37

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48



**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48

US3432094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:42:03

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:31:57**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:42:03

US3432094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:42:14

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:42:14

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered '09:58'	(b) (4), (b) (6)	08 Oct 2020 17:42:14

**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '8 Oct 2020 09:58'	System	08 Oct 2020 17:42:14

US3432094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:42:17



**US3432094**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered '1'	System	08 Oct 2020 17:42:17

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 64'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-13T12:08:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5233480e-f819-476d-82e5-7ef08a126599'	System	13 Oct 2020 16:08:34
User entered 'No (N)'	System	13 Oct 2020 16:08:34

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Have you been exposed to someone with 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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-13T12:08:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5233480e-f819-476d-82e5-7ef08a126599'	System	13 Oct 2020 16:08:34
User entered 'No (N)'	System	13 Oct 2020 16:08:34

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-13T12:08:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5233480e-f819-476d-82e5-7ef08a126599' User entered '13 Oct 2020 12:08:30'	System	13 Oct 2020 16:08:34
	System	13 Oct 2020 16:08:34

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 71'	System	11 Aug 2020 19:45:55



US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

[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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-20T12:04:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'd19a2ab5-7ed8-412b-91fc-f768567dac2c'	System	20 Oct 2020 16:05:23
User entered 'No (N)'	System	20 Oct 2020 16:05:23

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

Have you been exposed to someone with 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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-20T12:04:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'd19a2ab5-7ed8-412b-91fc-f768567dac2c'	System	20 Oct 2020 16:05:23
User entered 'No (N)'	System	20 Oct 2020 16:05:23

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-20T12:04:48', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'd19a2ab5-7ed8-412b-91fc-f768567dac2c' User entered '20 Oct 2020 12:04:48'	System	20 Oct 2020 16:05:23
	System	20 Oct 2020 16:05:23

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 78'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c' User entered 'Yes (Y)'	System	29 Oct 2020 16:08:57
	System	29 Oct 2020 16:08:57

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

Have you been exposed to someone with 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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c' User entered 'No (N)'	System	29 Oct 2020 16:08:57
	System	29 Oct 2020 16:08:57



US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

[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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c' User entered 'No (N)'	System	29 Oct 2020 16:08:57
	System	29 Oct 2020 16:08:57

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c'	System	29 Oct 2020 16:08:57
User entered 'Yes (Y)'	System	29 Oct 2020 16:08:57

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Please 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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c'	System	29 Oct 2020 16:08:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Oct 2020 16:08:57

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c' User entered '29 Oct 2020 12:08:46'	System	29 Oct 2020 16:08:57
	System	29 Oct 2020 16:08:57

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 92'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:57

[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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-11-11T12:36:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b3462f2a-f788-40db-b71b-7b513d195c73'	System	11 Nov 2020 17:36:40
User entered 'No (N)'	System	11 Nov 2020 17:36:40



**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

Have you been exposed to someone with 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 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-11-11T12:36:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b3462f2a-f788-40db-b71b-7b513d195c73'	System	11 Nov 2020 17:36:40
User entered 'No (N)'	System	11 Nov 2020 17:36:40

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-11-11T12:36:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b3462f2a-f788-40db-b71b-7b513d195c73' User entered '11 Nov 2020 12:36:35'	System	11 Nov 2020 17:36:40
	System	11 Nov 2020 17:36:40

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:26:14
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 99'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[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)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Have you been exposed to someone with 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)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Please 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)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[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)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05



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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Please 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)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[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)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Please 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)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 19:45:55

**US3432094**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:09:41
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:00:05
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 19:45:55



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:00:05

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:00:05



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:00:05

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:00:05

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:00:05

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:00:05

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:00:05

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:00:05



**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:31:57**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:00:05

**US3432094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 15:59:12

**US3432094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 15:59:12

**US3432094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Nov 2020 15:59:12

**US3432094**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 15:59:12



**US3432094**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 15:59:18

**US3432094**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:00:48
User entered 'I'	System	03 Nov 2020 15:59:18

**US3432094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Phoebe Cunningham (b) (4)	21 Dec 2020 18:13:31

**US3432094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Phoebe Cunningham (b) (4)	21 Dec 2020 18:13:31

**US3432094**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Phoebe Cunningham (b) (4)	21 Dec 2020 18:13:31

US3432094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:57

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Pt. in ICU at the time of call, but being monitored through EPIC. Will attempt follow-up if Pt's condition improves.'	Phoebe Cunningham (b) (4)	21 Dec 2020 18:13:31

**US3432094**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	05 Jan 2021 15:33:53

**US3432094**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User entered 'I'	System	05 Jan 2021 15:33:53



**US3432094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	05 Jan 2021 15:34:10

**US3432094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5 Jan 2021'	Kathleen Garvey (b) (4)	05 Jan 2021 15:34:10

**US3432094**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	05 Jan 2021 15:34:10

US3432094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:57

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Kathleen Garvey (b) (4)	05 Jan 2021 15:34:10

US3432094

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	05 Jan 2021 15:34:17

**US3432094**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User entered 'I'	System	05 Jan 2021 15:34:17

**US3432094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 15:58:23

**US3432094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '05 Feb 2021'	(b) (4), (b) (6)	05 Feb 2021 15:58:23



**US3432094**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:31:57**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Feb 2021 15:58:23

US3432094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:57

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 15:58:23

**US3432094**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 15:58:27

**US3432094**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:22:52
User entered 'I'	System	05 Feb 2021 15:58:27

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:33

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:33

US3432094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:57

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:33

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User entered 'VISIT4'	System	31 Mar 2021 20:13:33



US3432094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38

US3432094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User entered empty.	System	31 Mar 2021 20:13:38

US3432094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38

US3432094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38



**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User entered empty.	System	31 Mar 2021 20:13:38

US3432094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User entered empty.	System	31 Mar 2021 20:13:38

US3432094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User entered empty.	System	31 Mar 2021 20:13:38

US3432094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:57

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:38

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User entered empty.	System	31 Mar 2021 20:13:38

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27



**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:31:57**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27

US3432094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:57

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:41

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:31:57**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:41

US3432094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:57

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:45

US3432094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:57

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:45

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:45

**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User entered empty.	System	31 Mar 2021 20:13:45

US3432094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:57

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 20:13:53



**US3432094**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:31:27
User entered 'I'	System	31 Mar 2021 20:13:53

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:44

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:44

US3432094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:57

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:44

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:31:57**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 21:21:44

US3432094

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:31:57

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 10:17:40
User closed query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 10:17:39
Query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' answered with 'subject unable to come to site to sign updated consent form' (Site from DM).	Julia Klopfer (b) (4) (b) (4)	22 Apr 2021 15:20:30
User opened query 'Per CDM; Per IRT: Informed Consent Date is missing; Kindly update the data, Else clarify. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 08:16:46
Query 'Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box' answered with 'participant is unable to come to site due to SAEs. Noted in source. Unblinded over the phone under amendment 6' (Site from DM).	Monica Feeley (b) (4) (b) (4)	07 Apr 2021 20:48:07
User opened query 'Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 19:11:43
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:38

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered '0'	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:38

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:38



**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Amendment 6 or later (Amendment 6 or later)'	Monica Feeley (b) (4)	31 Mar 2021 21:21:38
	(b) (4)	

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '6 Jan 2021'	Monica Feeley (b) (4)	31 Mar 2021 21:21:38
	(b) (4)	

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered 'mRNA-1273 (mRNA-1273)'	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:38

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'mRNA-1273 (mRNA-1273)'	Monica Feeley (b) (4)	31 Mar 2021 21:21:38
	(b) (4)	

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered 'mRNA-1273 (mRNA-1273)'	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:38

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Monica Feeley (b) (4)	31 Mar 2021 21:21:38
	(b) (4)	

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:21:38

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:31:57**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:21:38



**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:48

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 21:21:48
	(b) (4)	

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4) (b) (4)	31 Mar 2021 21:21:48

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:31:57**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:21:48

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:31:57**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Monica Feeley (b) (4)	31 Mar 2021 21:21:53
	(b) (4)	

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:31:57**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 21:21:53
	(b) (4)	

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:31:57**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	31 Mar 2021 21:21:53
	(b) (4)	

**US3432094**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:31:57**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 21:21:53



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:31:57**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:42:27
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:15:38

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:57

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Arthropod bite - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:36:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:36:40
Data point term sent to Coder	System	10 Sep 2020 17:18:04
User entered 'Insect Bite'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	12 Sep 2020 16:06:36
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	10 Sep 2020 17:17:29
User entered '7 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:17:29



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 17:26:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Oct 2020 21:15:59
User entered '14 Sep 2020' reason for change: New Information	Natalie Izaguirre (b) (4)	08 Oct 2020 21:15:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	01 Oct 2020 17:27:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 17:27:06
User entered 'un Sep 2020' (non-conformant).	(b) (4), (b) (6)	01 Oct 2020 17:27:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 17:26:58
User entered ' Sep 2020' (non-conformant).	(b) (4), (b) (6)	01 Oct 2020 17:26:58
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

**Hospital Discharge Date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 17:26:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:22:52
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:17:29

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:57

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:35
Data point term sent to Coder	System	24 Nov 2020 16:12:51
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:12:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:12:20
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:12:17
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	12 Nov 2020 22:42:43
User closed query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:12:41
Data point term sent to Coder	System	03 Nov 2020 16:06:50
User entered 'IPSILATERAL LYMPHADENOPATHY (RIGHT POSTERIOR CERVICAL CHAIN, RIGHT POSTERIOR MANDIBULAR, RIGHT SUPRACLAVICULAR)' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Nov 2020 16:06:30

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:57

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly.  ' answered with 'Condition has been updated as ipsilateral, same side as vaccination' (Site from DM). Data point term sent to Coder	(b) (4), (b) (6)	03 Nov 2020 16:06:02
User entered 'LYMPHADENOPATHY (RIGHT POSTERIOR CERVICAL CHAIN, RIGHT POSTERIOR MANDIBULAR, RIGHT SUPRACLAVICULAR) - IPSILATERAL TO VACCINATION SITE' reason for change: Per Query Resolution	System	03 Nov 2020 16:05:49
Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 16:05:18
User entered 'LYMPHADENOPATHY (RIGHT POSTERIOR CERVICAL CHAIN, RIGHT POSTERIOR MANDIBULAR, RIGHT SUPRACLAVICULAR) - ipsilateral to vaxx site' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Nov 2020 16:04:57
User opened query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 16:04:57
User closed query 'Per DM CLR: Please specify the location of LYMPHADENOPATHY (e.g., Both Axillas, Right Groin, etc). 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)	02 Nov 2020 01:56:18
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 17:54:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	09 Oct 2020 07:21:17
Data point term sent to Coder	System	09 Oct 2020 07:21:17
		08 Oct 2020 22:43:43

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1844 of 2991

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:57

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify the location of LYMPHADENOPATHY (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Natalie Izaguirre (b) (4)	08 Oct 2020 22:43:20
Coding entries removed.	Natalie Izaguirre (b) (4)	08 Oct 2020 22:43:10
User entered 'LYMPHADENOPATHY (right posterior cervical chain, right posterior mandibular, right supraclavicular)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	08 Oct 2020 22:43:10
User opened query 'Per DM CLR: Please specify the location of LYMPHADENOPATHY (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.	(b) (4), (b) (6)	23 Sep 2020 08:31:58
' (Site from DM).		
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:20:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:20:43
Data point term sent to Coder	System	10 Sep 2020 17:19:06
User entered 'Lymphadenopathy'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:42:20
Query 'Data is required. Please provide.' answered with 'While this is the first day we know about this, the AE likely started before. ' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 17:20:17
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 17:19:04
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:19:04

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Oct 2020 17:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 17:39:56
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Oct 2020 17:39:56
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 17:38:48
User entered '08 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	08 Oct 2020 17:38:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:31:57

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 15:22:17
Query 'Data is required. Please provide.' answered with 'not captured' (Site from System).	Xhoi Mitre (b) (4)	10 Nov 2020 21:11:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 17:38:48
User entered empty.	System	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:19:04



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'Related (RELATED)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '1'	(b) (4), (b) (6)	10 Sep 2020 17:19:04



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 17:39:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:23:36
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:19:04

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:19:04

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:00:05
User entered 'USA-US078-2020-mRNA-1273-P301000015'	(b) (4), (b) (6)	22 Jan 2021 14:59:15



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this worsening AE and please note that the baseline MH condition of Meningioma is listed as resolved and there is no prior AE record that would support this worsening condition. Please update to record the baseline condition as appropriate or consider to remove the term Progression of as applicable. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 06:28:02
	(b) (4), (b) (6)	04 Dec 2020 17:51:45
Query 'Per DM CLR: Please review this worsening AE and please note that the baseline MH condition of Meningioma is listed as resolved and there is no prior AE record that would support this worsening condition. Please update to record the baseline condition as appropriate or consider to remove the term Progression of as applicable. Otherwise, clarify.' answered with 'participant reported to us that cancer was resolved in 2012 during enrollment when the physician investigator was collecting baseline medical history. However, now we have learned that is it ongoing.' (Site from DM).	Monica Feeley (b) (4)	04 Dec 2020 15:32:35
User opened query 'Per DM CLR: Please review this worsening AE and please note that the baseline MH condition of Meningioma is listed as resolved and there is no prior AE record that would support this worsening condition. Please update to record the baseline condition as appropriate or consider to remove the term Progression of as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 02:59:56
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Nervous system neoplasms malignant and unspecified NEC, HLT: Nervous system neoplasms unspecified malignancy NEC, PT: Meningioma, LLT: Meningioma - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 05:47:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 05:47:50
Data point term sent to Coder	System	29 Oct 2020 21:06:10
User entered 'Progression of Meningioma'	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:51:47
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:51:48
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:51:51
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:02
User entered '28 Oct 2020'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:04
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:05:33

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:05
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33



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Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query '. PV Query: For the event of meningioma, 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). DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 21:00:52
	(b) (4), (b) (6)	04 Dec 2020 17:52:07
User entered empty.	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:09
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:05:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

Severity

Audit	User	Time (GMT)
User closed query 'PV Query: As event resulted in hospitalization, and subject was in ICU for 24 days, please upgrade severity/intensity to more appropriate grade of 3 or 4. ' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:38:01
Query 'PV Query: As event resulted in hospitalization, and subject was in ICU for 24 days, please upgrade severity/intensity to more appropriate grade of 3 or 4. ' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	10 Feb 2021 15:09:00
DataPoint Un-verified.	Monica Feeley (b) (4)	10 Feb 2021 15:08:55
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Monica Feeley (b) (4)	10 Feb 2021 15:08:55
User opened query 'PV Query: As event resulted in hospitalization, and subject was in ICU for 24 days, please upgrade severity/intensity to more appropriate grade of 3 or 4. ' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 21:01:57
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Jan 2021 14:23:07
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	21 Jan 2021 14:22:34
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:12
User entered 'No (N)'	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:13
User entered '0'	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:15
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		21 Jan 2021 14:23:07
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		21 Jan 2021 14:23:07
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Jan 2021 14:23:07
User entered '1' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Jan 2021 14:23:07
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	21 Jan 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:16
User entered '0'	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33
	(b) (4)	



US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
User entered '23 Nov 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 17:52:18
User entered empty.	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33
	(b) (4)	

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge (23 Nov 2020 - 23 Dec 2020) summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:01:30
Query 'PV Query: Please send a hospital discharge (23 Nov 2020 - 23 Dec 2020) summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'discharge summary sent' (Site from Safety).	Monica Feeley (b) (4)	30 Apr 2021 19:21:35
User opened query 'PV Query: Please send a hospital discharge (23 Nov 2020 - 23 Dec 2020) summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:53:13
Query ' PV Query: For the event of altered mental status, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:52:39
User opened query ' PV Query: For the event of altered mental status, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:51:56
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
User entered '23 Dec 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:19

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: As event resulted in hospitalization, and subject was in ICU for 24 days, please upgrade severity/intensity to more appropriate grade of 3 or 4.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:38:07
Query 'PV Query: As event resulted in hospitalization, and subject was in ICU for 24 days, please upgrade severity/intensity to more appropriate grade of 3 or 4.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	10 Feb 2021 15:10:20
User opened query 'PV Query: As event resulted in hospitalization, and subject was in ICU for 24 days, please upgrade severity/intensity to more appropriate grade of 3 or 4.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:58:19
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:22
User entered empty.	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

Number of Days in ICU

Audit	User	Time (GMT)
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 16:58:39
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered with 'this is provided?' (Site from System).	Monica Feeley (b) (4)	21 Jan 2021 14:22:58
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	21 Jan 2021 14:22:34
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
User entered '24' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:23
User entered empty.	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:25
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:27
User entered '0'	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:28
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:30
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:32
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:58:28
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'EDC is updated as per the source' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:42:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:41:34
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:00:45
User entered 'Not Applicable (NOT APPLICABLE)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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Folder: Adverse Events

Form: Adverse Events (3)

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Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCG, if the AE started after the last dose, Action taken with IP should be recorded as Not Applicable. Please review and update as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 06:28:54
	(b) (4), (b) (6)	04 Dec 2020 17:52:38
Query 'Per CDM: As per CCG, if the AE started after the last dose, Action taken with IP should be recorded as Not Applicable. Please review and update as appropriate. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	04 Dec 2020 14:55:50
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Monica Feeley (b) (4)	04 Dec 2020 14:55:45
	(b) (4)	
User opened query 'Per CDM: As per CCG, if the AE started after the last dose, Action taken with IP should be recorded as Not Applicable. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 06:40:51
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:31:57

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Procedures recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:57:48
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Procedures recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	21 Jan 2021 14:16:45
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Jan 2021 14:16:41
User entered '0' reason for change: Data Entry Error	Monica Feeley (b) (4)	21 Jan 2021 14:16:41
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Procedures recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:19:06
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:42
User entered '1'	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:46:59
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'there are many con medications taken during this time. confirmed. look at dates' (Site from DM).	Monica Feeley (b) (4) (b) (4)	20 Apr 2021 20:32:25
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:06:00
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	21 Jan 2021 14:16:41
User entered '1' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	21 Jan 2021 14:16:41
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:47
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Monica Feeley (b) (4)	21 Jan 2021 14:16:41
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Monica Feeley (b) (4)	21 Jan 2021 14:16:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 17:52:48
User entered '0'	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: For the event of meningioma, 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)	18 Feb 2021 22:15:52
Query 'PV Query: For the event of meningioma, please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Feb 2021 22:14:53
User opened query 'PV Query: For the event of meningioma, please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:51:05
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:52:52
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33



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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = PARTICIPANT REPORTED THAT MENINGIOMA WAS RESOLVED IN 2012 (HAD A SURGICAL RESECTION). However, please review and verify if this should be recorded as part of the subject's Medical History (i.e., Surgical Operation). If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:25:47
Query 'Per DM CLR: Narrative = PARTICIPANT REPORTED THAT MENINGIOMA WAS RESOLVED IN 2012 (HAD A SURGICAL RESECTION). However, please review and verify if this should be recorded as part of the subject's Medical History (i.e., Surgical Operation). If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'this has been updated in medical history' (Site from DM).	Monica Feeley (b) (4) (b) (4)	22 Apr 2021 15:02:32
User closed query 'PV Query: Please provide results of diagnostic test MRI from 10/28.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:25:24
User closed query 'PV Query: For the event of meningioma, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:25:13
User closed query 'Per DM CLR: Narrative = IN RETROSPECT, SERIAL MRI OVER THE LAST 2-3 YEARS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:44:36
Query 'PV Query: Please provide results of diagnostic test MRI from 10/28.' answered with 'please see updated narrative. (interval increased nodular enhancement adjacent to the left parietal craniotomy site including a L parasagittal component extending into the superior sagittal sinus). ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	20 Apr 2021 20:34:36

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'WE HAD REPORTED SURGERY AND HOSPITALIZATION FOR MENINGIOMA AS A SEPARATE SAE, WHICH WE SUBSUMED AND ARE COMBINING IN THIS AE. AT ENROLLMENT, PARTICIPANT REPORTED THAT MENINGIOMA WAS RESOLVED IN 2012 (HAD A SURGICAL RESECTION). IN RETROSPECT, SERIAL MRI OVER THE LAST 2-3 YEARS SHOWED SOME GROWTH TO HIS MENINGIOMA, FOR WHICH AN ELECTIVE SURGERY WAS PLANNED AFTER THE RESULT OF THE MRI DONE ON 10/28/2020 (interval increased nodular enhancement adjacent to the left parietal craniotomy site including a L parasagittal component extending into the superior sagittal sinus). PARTICIPANT HAD A CRANIOPLASTY AND CRANIECTOMY FOR MENINGIOMA. WHILE IN THE HOSPITAL, PARTICIPANT THEN SUFFERED FROM AN INTRA-OPERATIVE MEDICATION INDUCED HYPERTENSIVE INTRAPARENCHYMAL HEMORRHAGE.' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	20 Apr 2021 20:34:20
Query 'PV Query: For the event of meningioma, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no relevant laboratory results. diagnostic test of MRI shown' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	20 Apr 2021 20:32:02
Query 'Per DM CLR: Narrative = IN RETROSPECT, SERIAL MRI OVER THE LAST 2-3 YEARS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'please note that meningioma is already captured in the medical history. this encompasses the MRIs.' (Site from DM).	Monica Feeley (b) (4) (b) (4)	20 Apr 2021 20:31:22
User closed query 'Per DM CLR: Narrative = MRI DONE ON 10/28/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	19 Apr 2021 13:34:33

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = MRI DONE ON 10/28/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'please see con procedure for MRI on 28OCT2020' (Site from DM).	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 18:37:23
User opened query 'Per DM CLR: Narrative = MRI DONE ON 10/28/2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:05:53
User opened query 'Per DM CLR: Narrative = IN RETROSPECT, SERIAL MRI OVER THE LAST 2-3 YEARS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:05:48
User opened query 'Per DM CLR: Narrative = PARTICIPANT REPORTED THAT MENINGIOMA WAS RESOLVED IN 2012 (HAD A SURGICAL RESECTION). However, please review and verify if this should be recorded as part of the subject's Medical History (i.e., Surgical Operation). If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:05:41
User closed query 'PV Query: Please advise if intra-operative medication induced hypertensive intraparenchymal hemorrhage should be reported as an SAE.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:38:21
Query 'PV Query: Please advise if intra-operative medication induced hypertensive intraparenchymal hemorrhage should be reported as an SAE.' answered with 'we are submitting an ePIP regarding this. we will create a separate SAE if necessary.' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 15:10:11
User opened query 'PV Query: Please provide results of diagnostic test MRI from 10/28.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:58:54

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please advise if intra-operative medication induced hypertensive intraparenchymal hemorrhage should be reported as an SAE.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:58:37
User opened query 'PV Query: For the event of meningioma, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:51:18
User entered 'We had reported surgery and hospitalization for meningioma as a separate SAE, which we subsumed and are combining in this AE. At enrollment, participant reported that meningioma was resolved in 2012 (had a surgical resection). In retrospect, serial MRI over the last 2-3 years showed some growth to his meningioma, for which an elective surgery was planned after the result of the MRI done on 10/28/2020. Participant had a cranioplasty and craniectomy for meningioma. While in the hospital, participant then suffered from an intra-operative medication induced hypertensive intraparenchymal hemorrhage.' reason for change: New Information	Monica Feeley (b) (4)	21 Jan 2021 14:22:34
User entered empty.	Xhoi Mitre (b) (4)	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 14:22:34
User entered '0'	System	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Oct 2020 21:05:33

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Jan 2021 14:22:34

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Folder: Adverse Events

Form: Adverse Events (5)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 14:54:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 14:54:58
Data point term sent to Coder	System	04 Dec 2020 14:53:50
User entered 'Injection Site pain'	Monica Feeley (b) (4)	04 Dec 2020 14:53:37
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:03:32
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:57:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	10 Feb 2021 15:57:46
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:24:33
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

US3432094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

US3432094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 06:25:58
Query 'Data is required. Please provide.' answered with 'not known' (Site from System).	Monica Feeley (b) (4)	04 Dec 2020 14:53:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Dec 2020 14:53:37
User entered empty.	System	04 Dec 2020 14:53:37
	Monica Feeley (b) (4)	04 Dec 2020 14:53:37
	(b) (4)	

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37



US3432094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 06:26:01
Query 'Data is required. Please provide.' answered with 'not known' (Site from System).	Monica Feeley (b) (4)	04 Dec 2020 14:53:48
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Dec 2020 14:53:37
User entered empty.	System	04 Dec 2020 14:53:37
	Monica Feeley (b) (4)	04 Dec 2020 14:53:37
	(b) (4)	

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 14:53:37

US3432094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:57

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

US3432094

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:31:57

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[None](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:53:37

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 14:53:37



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 14:53:37

US3432094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:31:57

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site swelling, LLT: Swelling of injection site - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 14:56:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 14:56:34
Data point term sent to Coder	System	04 Dec 2020 14:54:51
User entered 'Swelling at injection site'	Monica Feeley (b) (4)	04 Dec 2020 14:54:32
	(b) (4)	

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

US3432094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:31:57

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:03:42
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:58:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	10 Feb 2021 15:58:02
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria per protocol section 8.3.4 (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:24:41
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

US3432094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

US3432094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:31:57

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 06:26:10
Query 'Data is required. Please provide.' answered with 'not known' (Site from System).	Monica Feeley (b) (4)	04 Dec 2020 14:54:51
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Dec 2020 14:54:32
User entered empty.	System	04 Dec 2020 14:54:32
	Monica Feeley (b) (4)	04 Dec 2020 14:54:32
	(b) (4)	

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 14:54:32



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

US3432094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:31:57

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	07 Dec 2020 06:26:13
Query 'Data is required. Please provide.' answered with 'not known' (Site from System).	Monica Feeley (b) (4)	04 Dec 2020 14:54:53
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Dec 2020 14:54:32
User entered empty.	System	04 Dec 2020 14:54:32
	Monica Feeley (b) (4)	04 Dec 2020 14:54:32
	(b) (4)	

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

US3432094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:31:57

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

US3432094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:31:57

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

US3432094

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:31:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 14:54:32

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:00:58
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 20:03:12
User entered 'USA-US078-2020-mRNA-1273-P301000015'	(b) (4), (b) (6)	04 Jan 2021 20:03:07

US3432094

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: For altered mental status, please confirm if event term should be updated to encephalopathy.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:02:09
Query 'PV Query: For altered mental status, please confirm if event term should be updated to encephalopathy.' answered with 'confirmed it should not be. hospital records state "altered mental state"' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	30 Apr 2021 15:19:59
User opened query 'PV Query: For altered mental status, please confirm if event term should be updated to encephalopathy.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 11:46:09
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:00
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Mental disorders NEC, PT: Mental status changes, LLT: Mental status changes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Jan 2021 20:39:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Jan 2021 20:39:35
Data point term sent to Coder	System	02 Jan 2021 20:38:34
User entered 'Altered Mental Status'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:02
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:05
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:07
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:13
User entered '27 Dec 2020'	Jun Bai Park Chang	02 Jan 2021 20:37:53
	(b) (4)	

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:15
User entered empty.	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Jan 2021 20:37:53

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:16
User entered 'No (N)' reason for change: New Information	Monica Feeley (b) (4)	10 Feb 2021 17:52:41
User entered 'Yes (Y)'	Jun Bai Park Chang	02 Jan 2021 20:37:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:18
User closed query 'PV Query: For the event of altered mental status, please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:38:52
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 17:53:49
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	10 Feb 2021 17:53:49
Query 'PV Query: For the event of altered mental status, 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 'updated' (Site from Safety).	Monica Feeley (b) (4)	10 Feb 2021 17:52:48
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	10 Feb 2021 17:52:41
User entered '4 Jan 2021' reason for change: New Information	Monica Feeley (b) (4)	10 Feb 2021 17:52:41
User opened query 'PV Query: For the event of altered mental status, please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 21:05:02
User entered empty.	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:20
User entered empty.	Jun Bai Park Chang	02 Jan 2021 20:37:53
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Jan 2021 20:37:53

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:23
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:26
User entered '0'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:28
User entered '0'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Feb 2021 20:04:16
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'all is filled' (Site from System).	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 17:52:58
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	10 Feb 2021 17:51:55
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Jan 2021 13:41:09
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Participant has not been discharged.' (Site from System).	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:38:18
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	02 Jan 2021 20:37:53
User entered 'I'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: For altered mental status, discharge summary shows admission date as 29Dec2020. Please confirm if discharge date should be updated. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:09:51
Query 'PV Query: For altered mental status, discharge summary shows admission date as 29Dec2020. Please confirm if discharge date should be updated. If not, please clarify.' answered with 'no this should not be changed. participant was in the ED on 29DEC2020. They were admitted to the hospital on 30DEC2020 at 243am. ED is not considered hospital admission' (Site from Safety).	Monica Feeley (b) (4)	30 Apr 2021 15:24:39
User opened query 'PV Query: For altered mental status, discharge summary shows admission date as 29Dec2020. Please confirm if discharge date should be updated. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 11:46:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:33
User entered '30 Dec 2020'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: For the event of altered mental status, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:37:02
Query 'PV Query: For the event of altered mental status, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent discharge summary' (Site from Safety).	Monica Feeley (b) (4)	20 Apr 2021 20:29:33
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:35
User closed query 'PV Query: For the event of altered mental status, please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:39:01
Query 'PV Query: For the event of altered mental status, please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	10 Feb 2021 17:53:02
User entered '4 Jan 2021' reason for change: Per Query Resolution	Monica Feeley (b) (4)	10 Feb 2021 17:51:55
User opened query 'PV Query: For the event of altered mental status, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:55:08
User opened query 'PV Query: For the event of altered mental status, please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 21:05:25
User entered empty.	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please indicate if subject was Admitted to ICU. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:49:16
Query 'Per CDM: Please indicate if subject was Admitted to ICU. Thank you.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	20 Apr 2021 20:11:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Please indicate if subject was Admitted to ICU. Thank you.' (Site from DM).	Monica Feeley (b) (4)	20 Apr 2021 20:11:17
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 20:04:58
	Jun Bai Park Chang	02 Jan 2021 20:37:53
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:40
User entered 'Not Related (NOT RELATED)'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:41
User entered 'Not Related (NOT RELATED)'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:44
User entered 'Not Applicable (NOT APPLICABLE)'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:48:38
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'recorded in error, no medications given for altered mental state' (Site from DM).	Monica Feeley (b) (4)	20 Apr 2021 20:15:36
User entered '0' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Apr 2021 20:14:54
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:57:13
User entered '1'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR - RQ: Site's response noted. 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 response to this field.' canceled (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 19:41:45
User opened query 'Per DM CLR - RQ: Site's response noted. 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 response to this field.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:06:50
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:05:26
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'this has been updated' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 17:50:03
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:57:08
User entered 'I'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:47
User closed query 'PV Query: For the event of altered mental status, 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)	11 Feb 2021 16:39:09
Query 'PV Query: For the event of altered mental status, please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 17:54:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 17:53:49
User opened query 'PV Query: For the event of altered mental status, 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)	11 Jan 2021 21:04:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Please consider whether rectal ulcer, pneumonia, bilateral lower extremity deep vein thrombosis, gastrointestinal bleed, bacteremia, left posterior frontotemporal hemorrhagic venous infarct, superior sagittal sinus thrombosis, seizures, and adrenal insufficiency should be added as events.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:10:13
User closed query 'PV Query: Please provide units and normal reference ranges for labs. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:10:09
Query 'PV query: Please consider whether rectal ulcer, pneumonia, bilateral lower extremity deep vein thrombosis, gastrointestinal bleed, bacteremia, left posterior frontotemporal hemorrhagic venous infarct, superior sagittal sinus thrombosis, seizures, and adrenal insufficiency should be added as events.' answered with 'left posterior frontotemporal hemorrhagic venous infarct, superior sagittal sinus thrombosis, seizures- these are already covered under a separate SAE (INTRA-OPERATIVE MEDICATION INDUCED HYPERTENSIVE INTRAPARENCHYMAL HEMORRHAGE)	Monica Feeley (b) (4)	30 Apr 2021 15:48:48
rectal ulcer is covered under separate SAE (HEMATOCHEZIA)		
bacteremia and DVT are covered under separate SAE (progression of meningioma as well as the INTRA-OPERATIVE MEDICATION INDUCED HYPERTENSIVE INTRAPARENCHYMAL HEMORRHAGE). not sure if they requires a separate SAE because it occurred while in hospital?		
pneumonia is not confirmed. it is a hypothesis for the AMS.		
Will need to follow up about the DVT ' (Site from Safety).		

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:31:57

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide units and normal reference ranges for labs. If unknown, please indicate so.' answered with 'there are no labs of importance thus there are no units and reference ranges?' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	30 Apr 2021 15:20:37
User opened query 'PV query: Please consider whether rectal ulcer, pneumonia, bilateral lower extremity deep vein thrombosis, gastrointestinal bleed, bacteremia, left posterior frontotemporal hemorrhagic venous infarct, superior sagittal sinus thrombosis, seizures, and adrenal insufficiency should be added as events.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	28 Apr 2021 11:46:48
User opened query 'PV Query: Please provide units and normal reference ranges for labs. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	28 Apr 2021 11:46:37
User closed query 'PV Query: For the event of altered mental status, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	21 Apr 2021 14:37:22
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	21 Apr 2021 14:37:14
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID testing- all NP swabs, all negative (dates: 12/30/20, 12/31/20). see narrative' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	20 Apr 2021 20:18:12
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	20 Apr 2021 20:17:58

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WITH HISTORY OF MENINGIOMA S/P LEFT CRANIOTOMY FOR RESECTION AND CRANIOPLASTY (23NOV2020), PRESENTS TO ED FROM REHAB WITH ALTERED MENTAL STATUS ON 29DEC2020 AND ADMITTED ON 30DEC2020. REHABILITATION CENTER NOTES THAT PARTICIPANT HAS BECOME MORE FATIGUE AND LETHARGIC STARTING 27DEC2020. CT SCAN ON 29DEC2020 FOUND NO ABNORMALITIES. COVID testing- all NP swabs, all negative (dates: 12/30/20, 12/31/20)' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Apr 2021 20:17:58
Query 'PV Query: For the event of altered mental status, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'noted diagnostic test (CT scan of head) in the narrative- no abnormalities. no relevant laboratories' (Site from Safety).	Monica Feeley (b) (4)	20 Apr 2021 20:16:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:01:49
User closed query 'Per DM CLR: SAE Narrative = CT SCAN ON 29DEC2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 20:07:25
Query 'Per DM CLR: SAE Narrative = CT SCAN ON 29DEC2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'this has been updated' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 17:49:53
Query 'PV Query: For the event of altered mental status, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:55:55

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:31:57

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: For the event of altered mental status, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 20:55:42
User opened query 'Per DM CLR: SAE Narrative = CT SCAN ON 29DEC2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 11:57:01
User closed query 'PV Query: For the event of altered mental status, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 14:56:08
Query 'PV Query: For the event of altered mental status, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no relevant laboratory results' (Site from Safety).	Monica Feeley (b) (4)	21 Jan 2021 14:23:32
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 21:05:49
User opened query 'PV Query: For the event of altered mental status, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 21:04:20
User opened query 'PV Query: For the event of altered mental status, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 21:04:08

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant with history of meningioma s/p left craniotomy for resection and cranioplasty (23NOV2020), presents to ED from rehab with altered mental status on 29DEC2020 and admitted on 30DEC2020. Rehabilitation center notes that participant has become more fatigue and lethargic starting 27DEC2020. CT scan on 29DEC2020 found no abnormalities.'	Jun Bai Park Chang (b) (4)	02 Jan 2021 20:37:53



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Jan 2021 20:37:53

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Jan 2021 20:37:53

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 20:11:17

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:33
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:10
User entered 'USA-US078-2021-mRNA-1273-P301000013'	System	04 Feb 2021 12:47:05
User entered 'New'	(b) (4), (b) (6)	04 Feb 2021 12:47:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:35
User closed query 'PV Query: Please assess whether lower gastrointestinal bleeding due to rectal tube trauma and rectal ulcer meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 03:05:46
Query 'PV Query: Please assess whether lower gastrointestinal bleeding due to rectal tube trauma and rectal ulcer meets criteria for separate AE/SAE reporting.' answered with 'the rectal tube trauma and rectal ulcer both contributed to one event of hematochezia' (Site from Safety).	Monica Feeley (b) (4)	10 Feb 2021 17:43:22
User opened query 'PV Query: Please assess whether lower gastrointestinal bleeding due to rectal tube trauma and rectal ulcer meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:27:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Haematochezia, LLT: Hematochezia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 22:18:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 22:18:30
Data point term sent to Coder	System	03 Feb 2021 22:17:11
User entered 'Hematochezia'	Xhoi Mitre (b) (4)	03 Feb 2021 22:16:46

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:38
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:41
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:43
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:45
User entered '30 Jan 2021'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:52
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:48
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 19:04:17
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	03 Feb 2021 22:16:46

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:50
User entered '06 Feb 2021' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 19:04:17
User entered empty.	Xhoi Mitre (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:54
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 11:54:41
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:22:40
User entered empty.	System	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:56
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:10:57
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:11:05
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Feb 2021 13:55:35
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not needed' (Site from System).	Monica Feeley (b) (4)	04 Feb 2021 20:16:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Feb 2021 22:16:46
User entered 'I'	Xhoi Mitre (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:11:08
User entered '2 Feb 2021'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:11:10
User entered '05 Feb 2021' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 18:55:18
User entered empty.	Xhoi Mitre (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:11:12
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46



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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:11:34
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:11:32
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:11:36
User entered 'Not Applicable (NOT APPLICABLE)'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[None](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:37:43
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'there are medications taken during this hospitalization captured in con meds' (Site from Safety).	Monica Feeley (b) (4)	20 Apr 2021 20:46:55
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:27:38
User entered 'I'	Xhoi Mitre (b) (4)	03 Feb 2021 22:16:46



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:11:40
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 15:40:41
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	01 Apr 2021 19:05:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 19:04:17
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:23:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4)	03 Feb 2021 22:16:46

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 13:25:33
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'discharge summary sent' (Site from Safety).	Monica Feeley (b) (4)	30 Apr 2021 19:21:52
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:37:51
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:37:49
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'COVID testing in hospital- All NP swabs, all negative (dates: 2/2/21. 2/3/21)' (Site from Safety).	Monica Feeley (b) (4)	20 Apr 2021 20:50:48

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT STARTED HAVING HEMOTOCHESIA, BRBPR, IN THE SETTING OF RECENT LGIB DUE TO RECTAL TUBE TRAUMA AND RECTAL ULCER ON JAN 30TH 2021. 1-2X/ DAY SINCE. HAD 3 EPISODES ON 2/1/21. PRESENTED TO ED ON 2/2/21 AND ADMITTED LATER THAT DAY. HAD FLEXIBLE SIGMOIDOSCOPY 03FEB2021 SHOWING THE RECTAL ULCER. COVID testing in hospital- All NP swabs, all negative (dates: 2/2/21. 2/3/21)' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Apr 2021 20:50:45
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'had flexible sigmoidoscopy 03FEB2021 showing the rectal ulcer. no significant laboratory results' (Site from Safety).	Monica Feeley (b) (4)	20 Apr 2021 20:49:52
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Apr 2021 20:49:46
User entered 'PT STARTED HAVING HEMOTOCHESIA, BRBPR, IN THE SETTING OF RECENT LGIB DUE TO RECTAL TUBE TRAUMA AND RECTAL ULCER ON JAN 30TH 2021. 1-2X/ DAY SINCE. HAD 3 EPISODES ON 2/1/21. PRESENTED TO ED ON 2/2/21 AND ADMITTED LATER THAT DAY. had flexible sigmoidoscopy 03FEB2021 showing the rectal ulcer' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Apr 2021 20:49:46
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:11:53
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 11:55:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:31:57

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:55:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 16:27:42
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Feb 2021 22:20:10
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Feb 2021 22:20:10
User entered 'Pt started having hematochezia, BRBPR, in the setting of recent LGIB due to rectal tube trauma and rectal ulcer on Jan 30th 2021. 1-2X/day since. Had 3 episodes on 2/1/21. Presented to ED on 2/2/21 and admitted later that day.' reason for change: Data Entry Error	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:20:10
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Feb 2021 22:16:46
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 22:16:46



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Feb 2021 22:16:46

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:25:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:51
User entered 'USA-US078-2020-mRNA-1273-P301000015'	(b) (4), (b) (6)	17 Feb 2021 13:59:40

US3432094

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:31:57

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural haemorrhage, LLT: Intraoperative hemorrhage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 10:04:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 10:04:07
Data point term sent to Coder	System	16 Feb 2021 20:53:59
User entered 'Intra-operative medication induced hypertensive intraparenchymal hemorrhage'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:53
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:55
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:57
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:00
User entered '23 Nov 2020'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:02
User entered empty.	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:04
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

US3432094

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: For the event of intra-operative medication induced hypertensive intraparenchymal hemorrhage, 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)	27 Apr 2021 23:44:08
User entered empty.	Monica Feeley (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

US3432094

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:31:57

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: For the event of intra-operative medication induced hypertensive intraparenchymal hemorrhage, 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.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:44:12
User opened query 'PV Query: For the event of intra-operative medication induced hypertensive intraparenchymal hemorrhage, 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)	18 Feb 2021 22:19:46
User entered empty.	System	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

US3432094

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:31:57

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:10
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:16
User entered '1'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:19
User entered '23 Nov 2020'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:24
User entered '23 Dec 2020'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:26
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:31
User entered '24'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:35
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:37
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:39
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[None](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

US3432094

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:31:57

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:55:51
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'there are con medications recorded during this time period. ' (Site from DM).	Monica Feeley (b) (4) (b) (4)	20 Apr 2021 20:44:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:07:09
User entered 'I'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

US3432094

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:31:57

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:44
User opened query 'PV Query: For the event of intra-operative medication induced hypertensive intraparenchymal hemorrhage, 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)	18 Feb 2021 22:20:14
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56



**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

US3432094

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:31:57

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:03:48
User entered "This event occurred under the SAE "Progression of meningioma" while the participant was in the hospital for a planned craniectomy. We were instructed to enter this event as a separate AE. Occurred during left craniectomy for resection and cranioplasty (scheduled procedure planned for progression of meningioma). Event prolonged hospitalization."	Monica Feeley (b) (4) (b) (4)	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 20:53:56

**US3432094**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 20:53:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:31:57

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:58
User closed query 'Per DM CLR: Per Diary Dose 2 Day 4, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:20:53
Query 'Per DM CLR: Per Diary Dose 2 Day 4, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'tylenol PRN already listed on con meds. Thank you' (Site from DM).	Bruce Bausk (b) (4) (b) (4)	08 Mar 2021 22:27:01
User opened query 'Per DM CLR: Per Diary Dose 2 Day 4, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 02:39:03
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:58:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 01:17:13
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 01:17:13
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 21:59:56
User entered 'Levothyroxine'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Pre-existing hypothyroidism'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '150'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'ug (ug)'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once daily (QD)'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per protocol, required' (Site from System).	Julia Klopfer (b) (4)	11 Aug 2020 22:14:09
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:59:38
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 21:59:38

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 21:59:38

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 21:59:38



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:57

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 14:50:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 14:50:34
	(b) (4)	
Data point term sent to Coder	System	04 Dec 2020 14:48:42
Coding entries removed.	Monica Feeley (b) (4)	04 Dec 2020 14:48:15
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 14:55:25
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 14:55:25
	(b) (4)	
Data point term sent to Coder	System	18 Aug 2020 14:54:11
Coding entries removed.	Monica Feeley (b) (4)	18 Aug 2020 14:53:57
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:02:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:02:18
Data point term sent to Coder	System	11 Aug 2020 22:00:58
User entered 'Aspirin'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:58:19
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' answered with 'updated to reflect indication' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:34:00
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:33:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:33:46
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:40:14
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4)	
User entered 'Cardiovascular prophylaxis' reason for change: Per Query Resolution	Monica Feeley (b) (4)	04 Dec 2020 14:48:15
	(b) (4)	
User closed query 'Please use full form of CAD' (Site from CRA).	(b) (4), (b) (6)	18 Aug 2020 20:18:51
	(b) (4)	
Query 'Please use full form of CAD' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	18 Aug 2020 14:54:02
	(b) (4)	
User entered 'Coronary Artery Disease' reason for change: Per Query Resolution	Monica Feeley (b) (4)	18 Aug 2020 14:53:57
	(b) (4)	
User opened query 'Please use full form of CAD' (Site from CRA).	(b) (4), (b) (6)	15 Aug 2020 22:58:33
	(b) (4)	
User entered 'CAD'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '81'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once daily (QD)'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:31:48
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:48:01
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:51:10
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per protocol, required' (Site from System).	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:14:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:00:56
User entered 'UN UNK 1990'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:00:56

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:00:56

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: IRBESARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:04:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:04:24
Data point term sent to Coder	System	11 Aug 2020 22:03:04
User entered 'Irbesartan'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Hypertension'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '150'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'twice daily (BID)'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		15 Aug 2020 00:34:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:58
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:02:52
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 22:02:52

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:02:52

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:05:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:05:10
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 22:04:08
User entered 'Escitalopram'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4), (b) (6)	
User closed query 'Please mention indication on medical history.' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 22:46:48
Query 'Please mention indication on medical history.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	18 Aug 2020 14:58:56
	(b) (4)	
User opened query 'Please mention indication on medical history.' (Site from CRA).	(b) (4), (b) (6)	15 Aug 2020 23:02:19
	(b) (4)	
User entered 'Depression'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '10'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once daily (QD)'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		15 Aug 2020 00:34:47
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:51
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:04:04
User entered 'UN UNK 2003'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:04:04

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:04:04

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:07:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:07:10
Data point term sent to Coder	System	11 Aug 2020 22:06:11
User entered 'Bupropion'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Depression'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '100'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once daily (QD)'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		15 Aug 2020 00:34:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:44
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:05:26
User entered 'UN UNK 2015'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:05:26

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:05:26



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 14:58:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 14:58:59
	(b) (4)	
Data point term sent to Coder	System	18 Aug 2020 14:57:23
Coding entries removed.	Monica Feeley (b) (4)	18 Aug 2020 14:56:59
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:29:08
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:29:08
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 22:13:21
User entered 'Atorvastatin'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4), (b) (6)	
User closed query 'Please check and clarify Indication.' (Site from CRA).	(b) (4), (b) (6)	18 Aug 2020 20:19:22
Query 'Please check and clarify Indication.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	18 Aug 2020 14:57:04
	(b) (4)	
User entered 'Coronary Artery Disease' reason for change: Per Query Resolution	Monica Feeley (b) (4)	18 Aug 2020 14:56:59
	(b) (4)	
User opened query 'Please check and clarify Indication.' (Site from CRA).	(b) (4), (b) (6)	15 Aug 2020 22:56:32
	(b) (4)	
User entered 'Pre-existing'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '20'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once daily (QD)'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Per protocol, required' (Site from System).	Julia Klopfer (b) (4)	11 Aug 2020 22:13:37
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:12:43
User entered 'UN Jul 2020'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	04 Dec 2020 18:33:56
DataPoint Verified.	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
User entered 'No (N)'	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:12:43

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:12:43

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:57

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:07:36
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:07:36
	(b) (4)	
Data point term sent to Coder	System	11 Aug 2020 22:13:21
User entered 'Prilosec'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Esophageal reflux'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '20'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once daily (QD)'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		15 Aug 2020 00:34:58
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:30
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:13:16
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:13:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:13:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 15:38:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 15:38:45
Data point term sent to Coder	System	17 Sep 2020 15:37:37
User entered 'Tylenol'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORENESS AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:37:35
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORENESS AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'no AE ' (Site from DM).	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 14:48:35



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORENESS AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:02:47
User entered 'Soreness at Injection Site'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '1000'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'as needed (PRN)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:44



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '10 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '12 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User entered empty.	System	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User entered empty.	System	17 Sep 2020 15:36:44

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:32
User entered empty.	System	17 Sep 2020 15:36:44



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 07:48:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 07:48:47
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:48
Data point term sent to Coder	System	04 Dec 2020 17:03:47
User entered 'Ducolax'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:50
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:51
User entered 'constipation'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '10'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'as needed (PRN)'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Rectal (RECTAL)'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '23 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:03:37
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:03:37



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:03:37

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:03:37

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:00:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:00:55
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:11:52
User entered 'Colace'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	10 Feb 2021 20:06:24
User closed query 'Per DM CLR: For Con Meds #10 and 11 - Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:57:13
Query 'Per DM CLR: For Con Meds #10 and 11 - Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'there is no AE needed. this participant was hospitalized per the SAE for meningioma. this is a medication that is frequently given in the hospital.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:42:16
User opened query 'Per DM CLR: For Con Meds #10 and 11 - Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:33:56
DataPoint Verified.	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '50/5'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg/mL'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 00:21:59
	(b) (4), (b) (6)	
User closed query 'Please check frequency per the hospital EMR and edit.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 00:21:38
Query 'Please check frequency per the hospital EMR and edit.' answered with 'this is correct' (Site from CRA).	Monica Feeley (b) (4)	16 Dec 2020 13:43:13
	(b) (4)	
User opened query 'Please check frequency per the hospital EMR and edit.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 19:09:03
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 19:08:44
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4)	
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Nasogastric tube'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '23 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 14:09:06
DataPoint Un-verified.	Monica Feeley (b) (4)	16 Dec 2020 13:44:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	16 Dec 2020 13:44:42
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 14:09:04
User closed query 'Per hospital EMR: this is ongoing, please review and edit.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:09:03
Query 'Per hospital EMR: this is ongoing, please review and edit.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	16 Dec 2020 13:44:45
	(b) (4)	
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	16 Dec 2020 13:44:42
	(b) (4)	
User opened query 'Per hospital EMR: this is ongoing, please review and edit.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 19:07:28
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 19:06:09
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:35:31
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:34:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4), (b) (6)	
User entered '24 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:31:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:10:53
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Dec 2020 17:10:53

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:10:53

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 17:10:53

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	17 Dec 2020 14:08:25
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 14:08:23
User closed query 'Please consider removing as the other alternative (COLACE 50mg/5ml) was given' (Site from CRA).	Monica Feeley (b) (4)	16 Dec 2020 13:45:04
Query 'Please consider removing as the other alternative (COLACE 50mg/5ml) was given' answered with 'both were given' (Site from CRA).	Coder Import (b) (4)	10 Dec 2020 19:00:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTS YNOM: COLACE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Dec 2020 19:00:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	04 Dec 2020 19:00:22
User opened query 'Please consider removing as the other alternative (COLACE 50mg/5ml) was given' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 18:59:39
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
DataPoint Verified.	System	04 Dec 2020 17:11:51
Data point term sent to Coder	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
User entered 'Colace'	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'constipation'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '100'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Nasogastric tube'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '23 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	Monica Feeley (b) (4)	16 Dec 2020 13:45:16
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	16 Dec 2020 13:45:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	Monica Feeley (b) (4)	16 Dec 2020 13:45:16
	(b) (4)	
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	16 Dec 2020 13:45:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '24 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:11:34
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Dec 2020 17:11:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:11:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 17:11:34

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 17:14:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 17:14:01
	(b) (4)	
Data point term sent to Coder	System	04 Dec 2020 17:12:53
User entered 'Tylenol'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'pain after cranioplasty and craniectomy'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '650'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 14:09:23
User closed query 'Per hospital records: every 6 hrs PRN, per the records the was given on 24 & 27 Nov only, please check if frequency needs to be updated to PRN' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:09:21
Query 'Per hospital records: every 6 hrs PRN, per the records the was given on 24 & 27 Nov only, please check if frequency needs to be updated to PRN' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	16 Dec 2020 13:45:47
User entered 'Q6 HOURS PRN' reason for change: Data Entry Error	Monica Feeley (b) (4)	16 Dec 2020 13:45:44
User opened query 'Per hospital records: every 6 hrs PRN, per the records the was given on 24 & 27 Nov only, please check if frequency needs to be updated to PRN' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 18:39:26
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:38:02
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Q6 hours'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Nasogastric tube'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '24 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:22
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:12:22

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:12:22

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:12:22



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: OTHER CARDIAC STIMULANTS, PRODUCT: ATROPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 03:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 03:51:48
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:13:54
User entered 'Atropine'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 17:12:57

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Bradycardia'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'I'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'as needed (PRN)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '25 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:31:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:12:57
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:12:57



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:12:57

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:12:57

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:41:24
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: OFIRMEV - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 17:15:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 17:15:07
	(b) (4)	
Data point term sent to Coder	System	04 Dec 2020 17:13:54
User entered 'Ofirmev'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:00
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:01
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'pain after cranioplasty and craniectomy'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:03
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '100'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:04
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:06
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:07
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:09
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Q6 hours'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:11
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:13
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:15
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '25 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:18
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:20
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:31:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 18:42:22
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:13:32
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:13:32

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:13:32

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:13:32

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:31:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:31:56
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:21:08
Data point term sent to Coder	System	04 Dec 2020 17:14:55
User entered 'Lasix'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per DM CLR: For Con Meds #15, 16 and 17 - Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:06:45
User closed query 'Per DM CLR: Please update the indication to reflect the location of FLUID RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:06:44
Query 'Per DM CLR: Please update the indication to reflect the location of FLUID RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'general. location not needed' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:54:05
Query 'Per DM CLR: For Con Meds #15, 16 and 17 - Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'this is from hospitalization for meningioma progression. this is the indication for the medication' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:53:53
User opened query 'Per DM CLR: For Con Meds #15, 16 and 17 - Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:47:39
User opened query 'Per DM CLR: Please update the indication to reflect the location of FLUID RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:47:34
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User entered 'FLUID RETENTION Treatment'	Monica Feeley (b) (4)	04 Dec 2020 17:21:04
reason for change: Data Entry Error	(b) (4)	
User entered 'fluid retention prevention'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '10'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	04 Dec 2020 17:14:50
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	04 Dec 2020 17:14:50
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	04 Dec 2020 17:14:29
User entered 'once (ONCE)'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '24 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	04 Dec 2020 17:14:50
User entered '24 Nov 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	04 Dec 2020 17:14:50
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	04 Dec 2020 17:14:29
User entered '20 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:31:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:14:29

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User entered empty.	System	04 Dec 2020 17:14:29

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User entered empty.	System	04 Dec 2020 17:14:29

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:57
User entered empty.	System	04 Dec 2020 17:14:29

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:31:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:31:56
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:17:00
User entered 'Lasix'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 17:16:08



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per DM CLR: Please update the indication to reflect the location of FLUID RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:06:51
Query 'Per DM CLR: Please update the indication to reflect the location of FLUID RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'no location needed' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:54:19
User opened query 'Per DM CLR: Please update the indication to reflect the location of FLUID RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:48:00
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Fluid retention treatment'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '20'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once (ONCE)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '27 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '27 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:31:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:08

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User entered empty.	System	04 Dec 2020 17:16:08

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User entered empty.	System	04 Dec 2020 17:16:08



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:05
User entered empty.	System	04 Dec 2020 17:16:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:31:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:31:56
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:16:58
User entered 'Lasix'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 17:16:46

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per DM CLR: Please update the indication to reflect the location of FLUID RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:06:57
Query 'Per DM CLR: Please update the indication to reflect the location of FLUID RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'general no location needed' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:54:44
User opened query 'Per DM CLR: Please update the indication to reflect the location of FLUID RETENTION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:48:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'fluid retention treatment'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '10'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once (ONCE)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '27 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '27 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:31:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:16:46



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User entered empty.	System	04 Dec 2020 17:16:46

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User entered empty.	System	04 Dec 2020 17:16:46

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:11
User entered empty.	System	04 Dec 2020 17:16:46

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:55:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 00:55:46
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:18:01
User entered 'Lexapro'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'anxiety from surgery'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '20'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once daily (QD)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Nasogastric tube'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '27 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:15
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:17:15

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:17:15

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 17:17:15

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 17:19:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 17:19:01
	(b) (4)	
Data point term sent to Coder	System	04 Dec 2020 17:18:03
User entered 'Dilaudid'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'severe pain after cranioplasty and craniectomy'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	10 Feb 2021 20:07:14
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of dosage range. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:55:09
Query 'Per DM CLR: Please provide the actual dose for this medication instead of dosage range. Update the Dose and Dose Unit fields as appropriate.' answered with 'this is what was in the hospital record' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:49:10
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of dosage range. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:33:56
DataPoint Verified.	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
User entered '0.5-1'	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 14:10:06
User closed query 'per source EMR: frequency is every 4 hrs PRN, please review and edit frequency as required.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:10:04
Query 'per source EMR: frequency is every 4 hrs PRN, please review and edit frequency as required.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	16 Dec 2020 13:46:04
User entered 'Q4 HOURS PRN' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 13:45:59
User opened query 'per source EMR: frequency is every 4 hrs PRN, please review and edit frequency as required.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 19:17:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 19:16:22
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Q4 hours'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Nasogastric tube'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '01 Dec 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:17:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:17:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:17:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:17:59

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:26:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:26:54
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:19:05
User entered 'Hydralazine'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 17:18:30



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	10 Feb 2021 20:07:24
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'this is from hospitalization for meningioma progression. this is the indication for the medication that was taken during this time' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:55:36
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:55:45
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'high blood pressure'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:31:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '5-10'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 14:10:15
User closed query 'per source EMR: frequency is every 4 hrs PRN, please review and edit frequency as required.' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 14:10:13
Query 'per source EMR: frequency is every 4 hrs PRN, please review and edit frequency as required.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	16 Dec 2020 13:46:28
User entered 'Q4 HOURS PRN' reason for change:	(b) (4)	
Data Entry Error	Monica Feeley (b) (4)	16 Dec 2020 13:46:20
User opened query 'per source EMR: frequency is every 4 hrs PRN, please review and edit frequency as required.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 19:18:38
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 19:18:31
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Q4 hours'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:31:57

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '03 Dec 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:18:30
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:18:30

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:18:30



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:18:30

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Feb 2021 11:03:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Feb 2021 11:03:50
Data point term sent to Coder	System	10 Feb 2021 15:56:10
Coding entries removed.	Monica Feeley (b) (4)	10 Feb 2021 15:56:00
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 13:36:26
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'confirmed. not prior to screening therefore not exclusionary for enrollment.' (Site from DM).	Jessica Cauley (b) (4)	05 Jan 2021 14:56:35
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 13:54:20

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 00:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 00:12:51
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:20:07
User entered 'Dexamethasone'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:24:11
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4)	05 Mar 2021 18:36:50
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:09:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per DM CLR: Please update the indication to reflect the location and/or type of INFLAMMATION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:07:33
Query 'Per DM CLR: Please update the indication to reflect the location and/or type of INFLAMMATION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'general' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:56:07
DataPoint Un-verified.	Monica Feeley (b) (4)	10 Feb 2021 15:56:00
User entered 'INFLAMMATION (general)' reason for change: Data Entry Error	Monica Feeley (b) (4)	10 Feb 2021 15:56:00

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location and/or type of INFLAMMATION. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	01 Feb 2021 07:59:29
	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Inflammation'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 14:11:15
DataPoint Un-verified.	Monica Feeley (b) (4)	16 Dec 2020 13:54:13
User entered 'Tapered Dosage' reason for change:	(b) (4)	
Data Entry Error	Monica Feeley (b) (4)	16 Dec 2020 13:54:13
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '8'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 14:11:17
DataPoint Un-verified.	Monica Feeley (b) (4)	16 Dec 2020 13:54:13
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Monica Feeley (b) (4)	16 Dec 2020 13:54:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4)	
DataPoint Un-verified.	Monica Feeley (b) (4)	16 Dec 2020 13:54:13
	(b) (4)	
User entered '8 mg 04DEC20-05DEC20; 6 mg 05DEC2020-09DEC2020; 4 mg 09DEC2020-12DEC2020; 2 mg 12DEC2020-ongoing' reason for change: Data Entry Error	Monica Feeley (b) (4)	16 Dec 2020 13:54:13
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
	(b) (4)	
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
	(b) (4), (b) (6)	05 Mar 2021 06:53:22
User closed query 'Per CDM: Twice daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:46:15
Query 'Per CDM: Twice daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:46:03
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 16:46:03
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 16:46:03
User entered 'twice daily (BID)' reason for change: Per Query Resolution	(b) (4), (b) (6)	17 Feb 2021 18:11:21
User opened query 'Per CDM: Twice daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 00:08:16
User signature succeeded.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:19:20
User entered 'other (OTHER)'	Monica Feeley (b) (4)	(b) (4)

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 16:46:03
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 16:46:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 16:46:03
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Q12 hours'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Nasogastric tube'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 00:22:57
User closed query 'Per source EMR dose taper is noted from Dec05, if its given then please update EDC with stop dates and new entries.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 00:22:49
Query 'Per source EMR dose taper is noted from Dec05, if its given then please update EDC with stop dates and new entries.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	16 Dec 2020 13:54:17
	(b) (4)	
User opened query 'Per source EMR dose taper is noted from Dec05, if its given then please update EDC with stop dates and new entries.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 19:29:12
DataPoint Un-verified.	(b) (4), (b) (6)	04 Dec 2020 19:28:22
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '04 Dec 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:19:20
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Mar 2021 16:46:03
User entered empty.	System	04 Dec 2020 17:19:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 16:46:03
User entered empty.	System	04 Dec 2020 17:19:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 16:46:03
User entered empty.	System	04 Dec 2020 17:19:20

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 00:31:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 00:31:52
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:20:06
User entered 'Heparin'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 20:07:41
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'no underlying medication condition. this is given as an anticoagulant in the hospital' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 15:56:28
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:59:44
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'anticoagulant'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '490.1'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'units/hour'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'continuous'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '04 Dec 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
DataPoint Un-verified.	Monica Feeley (b) (4)	01 Apr 2021 19:24:48
Signature has been broken.	Monica Feeley (b) (4)	01 Apr 2021 19:24:48
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 19:24:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
DataPoint Un-verified.	Monica Feeley (b) (4)	01 Apr 2021 19:24:48
Signature has been broken.	Monica Feeley (b) (4)	01 Apr 2021 19:24:48
User entered '04 Dec 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	01 Apr 2021 19:24:48
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:31:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:02

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User entered empty.	System	04 Dec 2020 17:20:02

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User entered empty.	System	04 Dec 2020 17:20:02

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:21:19
User entered empty.	System	04 Dec 2020 17:20:02

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:14:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:14:47
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
Data point term sent to Coder	System	04 Dec 2020 17:21:07
User entered 'Esomeprazole'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'gastric reflux'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '20'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:31:57

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'once daily (QD)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Nasogastric tube'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '24 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:31:57

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:33:56
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 17:20:43
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:20:43

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 17:20:43



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 17:20:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFRADINE, PRODUCTSYNONYM: ANCEF [CEFRADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 17:00:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 17:00:46
Data point term sent to Coder	System	16 Dec 2020 13:56:01
User entered 'Ancef'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Bacterial Infection Prevention'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '2'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'g (g)'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'other (OTHER)'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Q8h PRN'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '07 Dec 2020'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4) (b) (4)	16 Dec 2020 13:55:08

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	16 Dec 2020 13:55:08
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 13:55:08

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 13:55:08

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Dec 2020 13:55:08

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:31:57

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:07:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:07:54
Data point term sent to Coder	System	11 Feb 2021 15:06:41
User entered 'Lasix'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:24:56
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' answered with 'no location needed' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:48:53
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:12:31
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Fluid Retention treatment'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '20'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'mg (mg)'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'once (ONCE)'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '15 Dec 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '15 Dec 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User entered empty.	System	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User entered empty.	System	11 Feb 2021 15:06:33

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:47
User entered empty.	System	11 Feb 2021 15:06:33

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:09:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 15:09:53
Data point term sent to Coder User entered 'Lasix'	System Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:08:42 11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:25:23
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4) (b) (4)	05 Mar 2021 18:37:04
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:12:50
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
User entered 'Fluid retention treatment'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:07:51



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '20'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'mg (mg)'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'once (ONCE)'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '20 Dec 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '20 Dec 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User entered empty.	System	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User entered empty.	System	11 Feb 2021 15:07:51

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:19:51
User entered empty.	System	11 Feb 2021 15:07:51

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: DUONEB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 09:42:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 09:42:55
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
Data point term sent to Coder	System	11 Feb 2021 15:09:44
User entered 'Duoneb'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:08:59



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:25:36
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4)	05 Mar 2021 18:37:16
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:14:18
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'shortness of breath'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '3'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'mL (mL)'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'other (OTHER)'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Q4 hour PRN'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Nebulization'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '23 Dec 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:08:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:08:59
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 15:08:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 15:08:59



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 15:08:59

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 11:37:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 11:37:56
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
Data point term sent to Coder	System	11 Feb 2021 15:10:45
User entered 'Heparin'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:10:27

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:26:11
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4)	05 Mar 2021 18:37:32
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:21:47
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Anticoagulant'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5000'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'units'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
	(b) (4)	
Signature has been broken.	Monica Feeley (b) (4)	05 Mar 2021 18:37:40
	(b) (4)	
User entered 'three times daily (TID)' reason for change: Data Entry Error	Monica Feeley (b) (4)	05 Mar 2021 18:37:40
	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
	(b) (4)	
User entered 'other (OTHER)'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
	(b) (4), (b) (6)	08 Mar 2021 18:26:27
User closed query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	Monica Feeley (b) (4)	05 Mar 2021 18:37:53
Query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'we have updated this to 3x daily' (Site from DM).	Monica Feeley (b) (4)	05 Mar 2021 18:37:40
Signature has been broken.	Monica Feeley (b) (4)	05 Mar 2021 18:37:40
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	17 Feb 2021 18:11:56
User opened query 'Per CDM: Three times daily is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User signature succeeded.	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
User entered 'Q8 hr'		

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Subcutaneous (SUBCUTANEOUS)'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:31:57

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Dec 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:10:27
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Mar 2021 18:37:40
User entered empty.	System	11 Feb 2021 15:10:27

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 18:37:40
User entered empty.	System	11 Feb 2021 15:10:27

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Mar 2021 18:37:40
User entered empty.	System	11 Feb 2021 15:10:27

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 15:13:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 15:13:53
Data point term sent to Coder	System	11 Feb 2021 15:12:46
User entered 'Dulcolax'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:27:02
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'please note that this is not an AE. this is given in the hospital to help with constipation that can occur. ' (Site from DM).	Monica Feeley (b) (4)	05 Mar 2021 18:35:11
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:34:09
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'constipation'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'mg (mg)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:12:18

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
Signature has been broken.	Monica Feeley (b) (4)	05 Mar 2021 18:34:54
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Monica Feeley (b) (4)	05 Mar 2021 18:34:54
Data Entry Error	(b) (4)	
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'other (OTHER)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User closed query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "as needed" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM). Query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "as needed" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'this has been updated to prn' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:27:16
Signature has been broken.	Monica Feeley (b) (4)	05 Mar 2021 18:35:22
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	05 Mar 2021 18:34:54
User opened query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "as needed" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:34:59
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'QD PRN'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '23 Dec 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:31:57

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:18
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 15:12:18

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 15:12:18

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 15:12:18

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:17:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:17:38
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
Data point term sent to Coder	System	11 Feb 2021 15:13:47
User entered 'Pepcid'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:12:55

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:31:57

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 15:14:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 15:14:38
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	11 Feb 2021 15:14:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 15:12:55
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:27:31
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' answered with 'there is no underlying medical condition. the participant was in the hospital for an SAE and was given this' (Site from DM).	Monica Feeley (b) (4)	05 Mar 2021 18:35:56
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:35:34
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'antacid'	Monica Feeley (b) (4)	11 Feb 2021 15:12:55



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '20'	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'mg (mg)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:12:55

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'twice daily (BID)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '23 Dec 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Yes (Y)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:12:55
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Feb 2021 15:12:55

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Feb 2021 15:12:55

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Feb 2021 15:12:55

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
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: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 15:16:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 15:16:53
Data point term sent to Coder	System	11 Feb 2021 15:15:50
User entered 'Hydrocortisone'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:24:52
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4) (b) (4)	05 Mar 2021 18:38:06
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:35:56
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
User entered 'adrenal insufficiency'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'mg (mg)'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'once daily (QD)'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '04 Jan 2021'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11 Jan 2021'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User entered '1'	System	11 Feb 2021 15:15:34

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User entered '1'	System	11 Feb 2021 15:15:34



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:10
User entered '804 (804)'	System	11 Feb 2021 15:15:34

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
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: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 15:17:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 15:17:53
Data point term sent to Coder	System	11 Feb 2021 15:16:53
User entered 'Hydrocortisone'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:24:40
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4) (b) (4)	05 Mar 2021 18:38:17
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:36:10
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
User entered 'adrenal insufficiency'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '15'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'mg (mg)'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'once (ONCE)'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '05 Jan 2021'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '05 Jan 2021'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:16:19



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User entered empty.	System	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User entered empty.	System	11 Feb 2021 15:16:19

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:15
User entered empty.	System	11 Feb 2021 15:16:19

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
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: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 15:33:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 15:33:54
Data point term sent to Coder	System	11 Feb 2021 15:33:03
User entered 'hydrocortisone'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:24:28
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4) (b) (4)	05 Mar 2021 18:38:29
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:36:26
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
User entered 'adrenal insufficiency'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '10'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'mg (mg)'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'once daily (QD)'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '06 Jan 2021'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '12 Jan 2021'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User entered '1'	System	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User entered '1'	System	11 Feb 2021 15:32:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:19
User entered '804 (804)'	System	11 Feb 2021 15:32:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:28:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:28:03
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
Data point term sent to Coder	System	11 Feb 2021 15:34:04
User entered 'Vancomycin'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:24:14
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4) (b) (4)	05 Mar 2021 18:38:41
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:36:38
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
User entered 'bacteremia'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:33:17



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UNK'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'UNK'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'unknown (UNKNOWN)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '06 Dec 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '04 Jan 2021'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User entered empty.	System	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User entered empty.	System	11 Feb 2021 15:33:17

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:25
User entered empty.	System	11 Feb 2021 15:33:17

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:25:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:25:54
Data point term sent to Coder	System	11 Feb 2021 15:34:04
User entered 'Ceftriaxone'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:23:57
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4) (b) (4)	05 Mar 2021 18:38:52
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:36:50
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
User entered 'Bacteremia'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '2'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'g (g)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'once daily (QD)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '23 Nov 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '24 Nov 2020'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User entered '1'	System	11 Feb 2021 15:33:59

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User entered '1'	System	11 Feb 2021 15:33:59



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:30
User entered '804 (804)'	System	11 Feb 2021 15:33:59

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:25:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Feb 2021 00:25:55
Data point term sent to Coder	System	11 Feb 2021 15:36:11
User entered 'Ceftriaxone'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'bacteremia'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:31:57

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:23:16
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'there is no AE that needs to be added. this, as well as the other con meds during this time frame, are for an SAE when the participant was hospitalized' (Site from DM).	Monica Feeley (b) (4) (b) (4)	05 Mar 2021 18:39:13
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:37:06
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	16 Feb 2021 00:08:16
User entered '2'	Monica Feeley (b) (4) (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'g (g)'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:31:57

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'once daily (QD)'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Intravenous (INTRAVENOUS)'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '02 Jan 2021'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '0'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '03 Feb 2021'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'No (N)'	Monica Feeley (b) (4)	11 Feb 2021 15:35:20



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User entered '1'	System	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User entered '1'	System	11 Feb 2021 15:35:20

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:20:37
User entered '804 (804)'	System	11 Feb 2021 15:35:20

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 19:29:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 19:29:06
Data point term sent to Coder	System	01 Apr 2021 19:28:17
User entered 'polyethylene glycol (Miralax)'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'constipation'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '17'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'g (g)'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	



US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'once daily (QD)'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '02 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Yes (Y)'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 19:28:09

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 19:28:09
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:28:09

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:28:09

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 19:28:09

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:31:57

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:04:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 11:04:21
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	04 Apr 2021 20:33:27
Data point term sent to Coder	System	01 Apr 2021 19:29:19
User entered 'heparin'	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 19:29:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'coagulant prophylaxis'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '5000'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Other (OTHER)'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:31:57

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'units/mL'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'three times daily (TID)'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:31:57

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Subcutaneous (SUBCUTANEOUS)'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:31:57

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '23 Dec 2020'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	



**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '0'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Yes (Y)'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4) (b) (4)	01 Apr 2021 19:29:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'No (N)'	Monica Feeley (b) (4)	01 Apr 2021 19:29:16
	(b) (4)	

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Apr 2021 19:29:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 19:29:16

**US3432094**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (38)**

**Generated On: 09 Jun 2021 17:31:57**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 19:29:16

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:31:57

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:58
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:50:10
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 16:20:26



US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:59:49
User entered '23 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 16:22:45
	(b) (4)	

**US3432094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:59:49
User entered 'Craniectomy'	Monica Feeley (b) (4)	04 Dec 2020 16:22:45
	(b) (4)	

**US3432094**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:59:49
User entered 'Medical History (MH)'	Monica Feeley (b) (4)	04 Dec 2020 16:22:45
	(b) (4)	

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:31:57

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:59:49
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 16:22:45
	(b) (4)	

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:57

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:35
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:59:49
User entered '23 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 16:22:57

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:35
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:59:49
User entered 'Cranioplasty'	Monica Feeley (b) (4)	04 Dec 2020 16:22:57

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:35
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:59:49
User entered 'Medical History (MH)'	Monica Feeley (b) (4)	04 Dec 2020 16:22:57

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:57

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:35
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 17:59:49
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 16:22:57



US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:38
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '29 Dec 2020'	Monica Feeley (b) (4)	10 Feb 2021 17:49:18

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:38
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'CT scan head'	Monica Feeley (b) (4)	10 Feb 2021 17:49:18

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:38
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	10 Feb 2021 17:49:18

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:31:57

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:38
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	10 Feb 2021 17:49:18

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:31:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '2 Feb 2021'	Monica Feeley (b) (4)	10 Feb 2021 17:49:33

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:31:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'CT Abdomen and pelvis'	Monica Feeley (b) (4)	10 Feb 2021 17:49:33

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	10 Feb 2021 17:49:33

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:31:57

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered empty.	Monica Feeley (b) (4)	10 Feb 2021 17:49:33



US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:31:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '28 Oct 2020'	Monica Feeley (b) (4)	01 Apr 2021 18:38:46

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:31:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'MRI Brain'	Monica Feeley (b) (4)	01 Apr 2021 18:38:46

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Apr 2021 18:38:46

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:31:57

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:42
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 18:38:46

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:31:57

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '03 Feb 2021'	Monica Feeley (b) (4)	01 Apr 2021 18:59:41

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:31:57

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Flexible Sigmoidoscopy'	Monica Feeley (b) (4)	01 Apr 2021 18:59:41

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:31:57

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Apr 2021 18:59:41

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:31:57

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:04:44
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered empty.	Monica Feeley (b) (4)	01 Apr 2021 18:59:41



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'USA-US078-2020-MRNA-1273-P301000015'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45



US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Lindsey'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Baden'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'MA'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered 'US'	System	25 Nov 2020 18:54:21

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 14:32:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
Signature has been broken.	System	17 Feb 2021 14:00:57
User entered '6'	System	17 Feb 2021 14:00:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	System	11 Feb 2021 16:40:57
User entered '4'	System	22 Jan 2021 15:00:35
User entered '3'	System	04 Jan 2021 20:03:34
User entered '2'	System	16 Dec 2020 20:41:26
User entered '1'	System	25 Nov 2020 18:54:21

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'USA-US078-2020-MRNA-1273-P301000015'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Lindsey'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Baden'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'MA'	System	25 Nov 2020 18:43:45



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered 'US'	System	25 Nov 2020 18:54:21

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 14:32:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
Signature has been broken.	System	17 Feb 2021 14:00:57
User entered '6'	System	17 Feb 2021 14:00:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	System	11 Feb 2021 16:40:57
User entered '4'	System	22 Jan 2021 15:00:35
User entered '3'	System	04 Jan 2021 20:03:34
User entered '2'	System	16 Dec 2020 20:41:26
User entered '1'	System	25 Nov 2020 18:54:21

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered '25/Nov/2020 18:54'	System	25 Nov 2020 18:54:21

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 18:54:21

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered	System	25 Nov 2020 18:43:45
'USA-US078-2020-MRNA-1273-P301000015'		

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Lindsey'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Baden'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'MA'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered 'US'	System	25 Nov 2020 18:54:21



US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 14:32:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
Signature has been broken.	System	17 Feb 2021 14:00:57
User entered '6'	System	17 Feb 2021 14:00:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	System	11 Feb 2021 16:40:57
User entered '4'	System	22 Jan 2021 15:00:35
User entered '3'	System	04 Jan 2021 20:03:34
User entered '2'	System	16 Dec 2020 20:41:26
User entered '1'	System	25 Nov 2020 18:54:21

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '16/Dec/2020 15:41'	System	16 Dec 2020 20:41:26

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 20:03:21
User entered 'I'	(b) (4), (b) (6)	16 Dec 2020 20:41:26

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'USA-US078-2020-MRNA-1273-P301000015'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Lindsey'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Baden'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'MA'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered 'US'	System	25 Nov 2020 18:54:21

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 14:32:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
Signature has been broken.	System	17 Feb 2021 14:00:57
User entered '6'	System	17 Feb 2021 14:00:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	System	11 Feb 2021 16:40:57
User entered '4'	System	22 Jan 2021 15:00:35
User entered '3'	System	04 Jan 2021 20:03:34
User entered '2'	System	16 Dec 2020 20:41:26
User entered '1'	System	25 Nov 2020 18:54:21



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '04/Jan/2021 20:03'	System	04 Jan 2021 20:03:34

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 15:00:23
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 20:03:34

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'USA-US078-2020-MRNA-1273-P301000015'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Lindsey'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Baden'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'MA'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered 'US'	System	25 Nov 2020 18:54:21

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 14:32:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
Signature has been broken.	System	17 Feb 2021 14:00:57
User entered '6'	System	17 Feb 2021 14:00:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	System	11 Feb 2021 16:40:57
User entered '4'	System	22 Jan 2021 15:00:35
User entered '3'	System	04 Jan 2021 20:03:34
User entered '2'	System	16 Dec 2020 20:41:26
User entered '1'	System	25 Nov 2020 18:54:21

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '22/Jan/2021 15:00'	System	22 Jan 2021 15:00:35



US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 16:39:34
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 15:00:35

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'USA-US078-2020-MRNA-1273-P301000015'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Lindsey'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Baden'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'MA'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered 'US'	System	25 Nov 2020 18:54:21

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 14:32:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
Signature has been broken.	System	17 Feb 2021 14:00:57
User entered '6'	System	17 Feb 2021 14:00:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	System	11 Feb 2021 16:40:57
User entered '4'	System	22 Jan 2021 15:00:35
User entered '3'	System	04 Jan 2021 20:03:34
User entered '2'	System	16 Dec 2020 20:41:26
User entered '1'	System	25 Nov 2020 18:54:21

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '11/Feb/2021 11:40'	System	11 Feb 2021 16:40:57

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 14:00:24
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 16:40:57



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'USA-US078-2020-MRNA-1273-P301000015'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45



US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Lindsey'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Baden'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'MA'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered 'US'	System	25 Nov 2020 18:54:21

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 14:32:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
Signature has been broken.	System	17 Feb 2021 14:00:57
User entered '6'	System	17 Feb 2021 14:00:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	System	11 Feb 2021 16:40:57
User entered '4'	System	22 Jan 2021 15:00:35
User entered '3'	System	04 Jan 2021 20:03:34
User entered '2'	System	16 Dec 2020 20:41:26
User entered '1'	System	25 Nov 2020 18:54:21

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
User entered '17/Feb/2021 09:00'	System	17 Feb 2021 14:00:57

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:32:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 14:00:57

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered	System	25 Nov 2020 18:43:45
'USA-US078-2020-MRNA-1273-P301000015'		



**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Yes (Y)'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'No (N)'	System	25 Nov 2020 18:43:45

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Lindsey'	System	25 Nov 2020 18:43:45



US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'Baden'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:54:14
User entered 'MA'	System	25 Nov 2020 18:43:45

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 20:41:10
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 18:19:42
User entered 'US'	System	25 Nov 2020 18:54:21

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 14:32:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 01:23:31
Signature has been broken.	System	17 Feb 2021 14:00:57
User entered '6'	System	17 Feb 2021 14:00:57
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '5'	System	11 Feb 2021 16:40:57
User entered '4'	System	22 Jan 2021 15:00:35
User entered '3'	System	04 Jan 2021 20:03:34
User entered '2'	System	16 Dec 2020 20:41:26
User entered '1'	System	25 Nov 2020 18:54:21

**US3432094**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000015**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:00:29
User entered '21/Apr/2021 10:32'	System	21 Apr 2021 14:32:21

US3432094

Folder: SAE USA-US078-2020-MRNA-1273-P301000015

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:00:29
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 14:32:21

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'USA-US078-2021-MRNA-1273-P301000013'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Yes (Y)'	System	04 Feb 2021 12:47:05



**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Yes (Y)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Lindsey'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Baden'	System	04 Feb 2021 12:47:05



**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'MA'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:41:43
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'US'	System	04 Feb 2021 12:47:32

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 14:38:27
User entered '2'	System	02 Apr 2021 15:42:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '1'	System	04 Feb 2021 12:47:32

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'USA-US078-2021-MRNA-1273-P301000013'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Yes (Y)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Yes (Y)'	System	04 Feb 2021 12:47:05



**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Lindsey'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Baden'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'MA'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:41:43
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'US'	System	04 Feb 2021 12:47:32

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 14:38:27
User entered '2'	System	02 Apr 2021 15:42:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '1'	System	04 Feb 2021 12:47:32



**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '04/Feb/2021 07:47'	System	04 Feb 2021 12:47:32

US3432094

Folder: SAE USA-US078-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:41:43
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 12:47:32

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'USA-US078-2021-MRNA-1273-P301000013'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Yes (Y)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Yes (Y)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05



**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Lindsey'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Baden'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'MA'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:41:43
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'US'	System	04 Feb 2021 12:47:32

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 14:38:27
User entered '2'	System	02 Apr 2021 15:42:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '1'	System	04 Feb 2021 12:47:32

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered '02/Apr/2021 11:42'	System	02 Apr 2021 15:42:10



US3432094

Folder: SAE USA-US078-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 14:38:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:33:27
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 15:42:10

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'USA-US078-2021-MRNA-1273-P301000013'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Yes (Y)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Yes (Y)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05



**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'No (N)'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Lindsey'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'Baden'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 12:47:25
User entered 'MA'	System	04 Feb 2021 12:47:05

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:21:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 15:41:43
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered 'US'	System	04 Feb 2021 12:47:32

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:31:57**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 14:38:27
User entered '2'	System	02 Apr 2021 15:42:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:08:16
User entered '1'	System	04 Feb 2021 12:47:32

**US3432094**

**Folder: SAE USA-US078-2021-MRNA-1273-P301000013**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:31:57**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:00:29
User entered '21/Apr/2021 10:38'	System	21 Apr 2021 14:38:27

US3432094

Folder: SAE USA-US078-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:31:57

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:00:29
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 14:38:27